Federal Register

Monday,
December 7, 2009

Part VI

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 requires the semi-annual issuance of an inventory of rulemaking actions under development throughout the Department with a view to offering summarized information about forthcoming regulatory actions for public review.

FOR FURTHER INFORMATION CONTACT: Dawn L. Smalls, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the spring 2009 Agenda was published.

Please note that the rulemaking abstracts included in this issue of the **Federal Register** relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities as required by the Regulatory Flexibility Act of 1980. Also available in this issue of the **Register** is the Department's submission to the fiscal year 2010 Regulatory Plan as required under Executive Order 12866.

The purpose of the Agenda is to encourage more effective public participation in the regulatory process, and HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda. The complete regulatory agenda of the Department is accessible online at www.reginfo.gov in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database.

Dated: October 9, 2009.

Dawn L. Smalls,

Executive Secretary, Department of Health and Human Services.

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
306	Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology **(Rulemaking Resulting From a Section 610 Review) (Reg Plan Seq No. 43)**	0991–AB58

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
307	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition **(Section 610 Review)**	0930–AA14

Substance Abuse and Mental Health Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
308	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
309	Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920–AA14
310	Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations	0920–AA23

HHS

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
311	Control of Communicable Diseases Foreign Quarantine	0920–AA12
312	Control of Communicable Diseases: Interstate Quarantine, Passenger Information	0920–AA27

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
313	Possession, Use and Transfer of Select Agents and Toxins **(Section 610 Review)**	0920–AA32

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
314	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06
315	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14
316	Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation **(Section 610 Review)**	0910–AG25
317	Over-the-Counter Human Drugs; Labeling Requirements **(Section 610 Review)**	0910–AG34

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
318	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics **(Reg Plan Seq No. 44)**	0910–AC52
319	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
320	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
321	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
322	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
323	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
324	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
325	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10
326	Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph	0910–AG12
327	Produce Safety Regulation **(Reg Plan Seq No. 46)**	0910–AG35
328	Modernization of the Current Food Good Manufacturing Practices Regulation **(Reg Plan Seq No. 47)**	0910–AG36

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
329	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
330	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
331	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
332	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
333	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors **(Reg Plan Seq No. 48)**	0910–AF27
334	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
335	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
336	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
337	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
338	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
339	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
340	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
341	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
342	Over-the-Counter (OTC) Drug Review—Acne Drug Products Containing Benzoyl Peroxide	0910–AG00
343	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents **(Reg Plan Seq No. 50)**	0910–AG33

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
344	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88
345	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
346	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
347	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
348	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
349	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
350	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
351	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
352	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
353	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
354	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
355	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910–AF95

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
356	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
357	Substances Prohibited From Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy	0910–AF46

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
358	Revisions to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2011 (CMS-4085-F)	0938–AP77
359	Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long-Term Care Hospital PPS and RY 2011 Rates (CMS-1498-P) **(Reg Plan Seq No. 53)**	0938–AP80
360	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-P) **(Reg Plan Seq No. 54)**	0938–AP82

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

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Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
361	Revisions to Payment Policies Under the Physician Fee Schedule for CY 2010 (CMS-1413-FC)	0938–AP40
362	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-FC)	0938–AP41
363	Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments (CMS-2291-F)	0938–AP53

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
364	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
365	Electronic Claims Attachments Standards (CMS-0050-IFC)	0938–AK62
366	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F) **(Section 610 Review)**	0938–AO53
367	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P) **(Section 610 Review)**	0938–AP32
368	State Flexibility for Medicaid Benefit Packages (CMS-2232-F4)	0938–AP72

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
369	Medicaid Graduate Medical Education (CMS-2279-F)	0938–AO95
370	Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)	0938–AP37
371	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-F)	0938–AP39
372	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-F)	0938–AP46
373	Home Health Prospective Payment System and Rate Update for CY 2010 (CMS-1560-F)	0938–AP55
374	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2010 (CMS-1538-F)	0938–AP56

Department of Health and Human Services (HHS) — Final Rule Stage

Office of the Secretary (OS)

306. ● HEALTH INFORMATION TECHNOLOGY: INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA FOR ELECTRONIC HEALTH RECORD TECHNOLOGY (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 43 in part II of this issue of the **Federal Register**.

RIN: 0991–AB58

Department of Health and Human Services (HHS) **Final Rule Stage**

Substance Abuse and Mental Health Services Administration (SAMHSA)

307. OPIOID DRUGS IN MAINTENANCE OR DETOXIFICATION TREATMENT OF OPIATE ADDITION (SECTION 610 REVIEW)

Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd–2; 42 USC 300xx–23; 42 USC 300x–27(a); 42 USC 300y–11

Abstract: This rule will amend the Federal opioid treatment program regulations. It will modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Timetable:

Action	Date	FR Cite
NPRM	06/19/09	74 FR 29153
NPRM Comment Period End	08/18/09	
Final Action	06/00/10	

Regulatory Flexibility Analysis Required: No

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, One Choke Cherry Rd, Suite 2–1063, Rockville, MD 20857
Phone: 240 276–2716

RIN: 0930–AA14

Department of Health and Human Services (HHS) **Long-Term Actions**

Substance Abuse and Mental Health Services Administration (SAMHSA)

308. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

Legal Authority: PL 106–310, 42 USC 290jj to 290jj–2

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2619

RIN: 0930–AA10

Department of Health and Human Services (HHS) **Proposed Rule Stage**

Centers for Disease Control and Prevention (CDC)

309. FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/CDC ANIMAL IMPORTATION REGULATIONS

Legal Authority: 42 USC 264

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents and vectors deemed to be of public health significance. Currently the regulations restrict the importation of nonhuman primates, dogs, cats, small turtles, etiologic agents, hosts and vectors, such as bats (42 CFR sections 71.53, 71.51, 71.52, 71.54). In addition, CDC has recently issued a series of emergency orders, restricting the importation of African rodents (42 CFR section 71.56) and civets (67 FR 3364-01). CDC is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the United States (42 CFR parts 71, Subpart F).

Timetable:

Action	Date	FR Cite
ANPRM	07/31/07	72 FR 41676
ANPRM Comment Period End	10/01/07	
Notice Extending ANPRM Comment Period	10/01/07	72 FR 55729
ANPRM Extended Comment Period End	12/01/07	
NPRM	06/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 16, Room 4324, MS E03, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA14

310. CONTROL OF COMMUNICABLE DISEASES: FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/CDC NONHUMAN PRIMATE REGULATIONS

Legal Authority: 42 USC 264

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the

introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Timetable:

Action	Date	FR Cite
NPRM	03/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 16, Room 4324, MS E03, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA23

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Final Rule Stage

311. CONTROL OF COMMUNICABLE DISEASES FOREIGN QUARANTINE

Legal Authority: 42 USC 243; 42 USC 248 and 249

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine isolation and conditional release of individuals suspected of carrying a quarantinable disease while respecting individual autonomy. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause a pandemic.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/20/06	
Final Action	03/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 16, Room 4324, MS E03, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA12

312. CONTROL OF COMMUNICABLE DISEASES: INTERSTATE QUARANTINE, PASSENGER INFORMATION

Legal Authority: 25 USC 198.231; 25 USC 1661; 42 USC 243; 42 USC 248; 42 USC 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response.

Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of individuals who may have been exposed. This provision, which was proposed section 70.4, would require any airline operating in interstate traffic to solicit and electronically submit certain passenger information to CDC for use in contact tracing when necessary to protect the vital interests of an individual, or other persons, in regard to significant health risks.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/30/06	
Final Action	03/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 16, Room 4324, MS E03, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA27

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Long-Term Actions

313. POSSESSION, USE AND TRANSFER OF SELECT AGENTS AND TOXINS (SECTION 610 REVIEW)

Legal Authority: PL 107–188

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: 1) the effect on human health as a reuslt of exposure to the agent or toxin, 2) the degree of contagiousness of the agent or toxin, 3) the methods by which the agent or toxin is transferred to humans, 4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent andy illness resulting from infection by the agent or toxin, and 5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Timetable:

Action	Date	FR Cite
NPRM	08/19/09	74 FR 159
NPRM Comment Period End	10/19/09	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Agency Contact: Robbin Weyant, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 20, Room 4202, 1600 Clifton Road NE., Atlanta, GA 30333
Phone: 404 718–2000

RIN: 0920–AA32

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Prerule Stage

314. FOOD LABELING: SAFE HANDLING STATEMENTS, LABELING OF SHELL EGGS; REFRIGERATION OF SHELL EGGS HELD FOR RETAIL DISTRIBUTION (SECTION 610 REVIEW)

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42 USC 243; 42 USC 264; 42 USC 271

Abstract: Section 101.17(h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) (21 CFR 16.5(a)(4)) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
Begin Review	12/00/09	
End Review	12/00/10	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1802
Fax: 301 436–2636
Email: geraldine.june@fda.hhs.gov

RIN: 0910–AG06

315. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (SECTION 610 REVIEW)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Abstract: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine

whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	12/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Room 6234, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301 847 8440
Email: pdma610(c)review@fda.hhs.gov

RIN: 0910–AG14

316. • STERILITY REQUIREMENT FOR AQUEOUS–BASED DRUG PRODUCTS FOR ORAL INHALATION (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360e; 21 USC 371; 21 USC 374; 21 USC 375

Abstract: FDA is undertaking a review of 21 CFR 200.51, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether this regulation on aqueous-based drug products for oral inhalation should be continued without change, or whether it should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for 21 CFR 200.51; (2) the nature of complaints or comments received concerning 21 CFR 200.51; (3) the complexity of 21 CFR 200.51; (4) the extent to which the regulation overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR 200.51.

Timetable:

Action	Date	FR Cite
Begin Review	05/01/09	
End Review	05/00/10	

Regulatory Flexibility Analysis Required: No

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6234, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301 847–8440
Email: howard.mullerjr@fda.hhs.gov

RIN: 0910–AG25

317. • OVER–THE–COUNTER HUMAN DRUGS; LABELING REQUIREMENTS (SECTION 610 REVIEW)

Legal Authority: 5 USC 610

Abstract: Part 201.66 (21 CFR section 201.66) established a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as Helvetica type style and the use of ''bullet points'' to introduce key information, and (3) minimum standards for type size and spacing. FDA issued the final rule to improve labeling after considering comments submitted to the agency following the publication of the proposed regulation in 1997. In 1999, FDA published the final rule and stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ''user-friendly'' visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in part 201.66. The purpose of this review is to determine whether the regulation in part 201.66 should be continued without change, or whether they should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in part 201.66; (2) the nature of the complaints or comments received concerning the regulation in part 201.66; (3) the complexity of the regulations in part 201.66; (4) the extent to which the regulation in part 201.66 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling standard regulations in part 201.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less

burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	08/03/09	
End Review of Current Regulation	02/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG34

Department of Health and Human Services (HHS) Food and Drug Administration (FDA)

Proposed Rule Stage

318. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Regulatory Plan: This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

RIN: 0910–AC52

319. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antihistamine labeling claims for the common cold.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/00	65 FR 51780
NPRM (Amendment) (Common Cold)	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF31

320. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action will address laxative drug products. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other professional labeling requirements for laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
NPRM (Professional Labeling—Sodium Phosphate)	06/00/10	
Final Action (Laxative Drug Products)	To Be	Determined
NPRM (Professional Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF38

321. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses combination products containing sunscreen and insect repellent ingredients. The second action addresses active ingredients reviewed under Time and Extent Applications. The third action addresses other effectiveness issues for OTC sunscreen drug products. The fourth action is the final action that addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM Comment Period End	12/26/07	
NPRM (Effectiveness)	05/00/10	

Action	Date	FR Cite
Final Action (UVA/UVB)	05/00/10	
NPRM (Sunscreen and Insect Repellent)	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF43

322. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The proposed rule addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/19/07	72 FR 71769
NPRM (Vaginal Contraceptive Drug Products)	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF44

323. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM addresses the use of benzocaine for weight control. The first final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final action will finalize the proposed rule for weight control products containing benzocaine.

Timetable:

Action	Date	FR Cite
NPRM (Phenylpropanol -amine)	12/22/05	70 FR 75988
NPRM (Benzocaine)	05/00/10	
Final Action (Phenylpropanol -amine)	05/00/10	
Final Action (Benzocaine)	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF45

324. OVER–THE–COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient ipecac syrup.

Timetable:

Action	Date	FR Cite
NPRM (IPECAC)	06/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF68

325. PROCESS CONTROLS FOR ANIMAL FEED INGREDIENTS AND MIXED ANIMAL FEED

Legal Authority: 21 USC 342; 21 USC 371; PL 110–85, sec 1002(a)(2)

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite
NPRM	10/00/10	

HHS—FDA **Proposed Rule Stage**

Action	Date	FR Cite
NPRM Comment Period End	01/00/11	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG10

326. PEDIATRIC DOSING FOR COUGH, COLD, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE; PROPOSED AMENDMENT OF FINAL MONOGRAPH

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	06/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG12

327. ● PRODUCE SAFETY REGULATION

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the **Federal Register**.

RIN: 0910–AG35

328. ● MODERNIZATION OF THE CURRENT FOOD GOOD MANUFACTURING PRACTICES REGULATION

Regulatory Plan: This entry is Seq. No. 47 in part II of this issue of the **Federal Register**.

RIN: 0910–AG36

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) **Final Rule Stage**

329. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

Abstract: The final rule would amend the postmarketing expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Final Action	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AA97

330. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been

several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	06/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC53

331. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

Legal Authority: PL 105–115, sec 121

Abstract: Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The final rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

Timetable:

Action	Date	FR Cite
NPRM	09/20/05	70 FR 55038
NPRM Comment Period End	12/19/05	
Final Action	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC55

332. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR parts 201.56, 201.57, and 201.80). Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug in pregnancy. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. The revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation.

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End	08/27/08	
Final Action	04/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF11

333. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Regulatory Plan: This entry is Seq. No. 48 in part II of this issue of the **Federal Register**.

RIN: 0910–AF27

334. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment—Ephedrine Single Ingredient)	07/13/05	70 FR 40237
Final Action (Technical Amendment)	11/30/07	72 FR 67639
Final Action (Amendment—Ephedrine Single Ingredient)	05/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF32

335. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes cough/cold combination products containing oral bronchodilators and expectorants.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
Final Action (Technical Amendment)	03/19/07	72 FR 12730
Final Action	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF33

336. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM (Phenylpropanol -amine)	12/22/05	70 FR 75988
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate)	08/01/06	71 FR 83358
Final Action (Phenylpropanol -amine)	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF34

337. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

Action	Date	FR Cite
Final Action (GRASE dosage forms)	09/00/10	
NPRM (Amendment)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF35

338. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses other miscellaneous issues relating to internal analgesics. The last document finalizes the Internal Analgesic Products monograph.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
NPRM (Amendment) (Overindulgence /Hangover)	To Be	Determined
Final Action (Required Warnings and Other Labeling)	04/29/09	74 FR 19385

Action	Date	FR Cite
Final Action (Correction)	06/30/09	74 FR 31177
Final Action (Technical Amendment)	12/00/09	
NPRM (Amendment) (Miscellaneous Issues)	09/00/10	
NPRM (Amendment) (Pediatric)	To Be	Determined
NPRM (Amendment) (Combinations With Sodium Bicarbonate)	To Be	Determined
Final Action (Internal Analgesics)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF36

339. OVER–THE–COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/06	71 FR 74474
Final Action	05/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF37

340. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses skin protectant products used to treat fever blisters and cold sores. The second action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	02/01/08	73 FR 6014
Final Action (Fever Blisters/Cold Sores)	06/00/10	
Final Action (Aluminum Acetate) (Technical Amendment)	03/06/09	74 FR 9759
Final Action (Diaper Rash)	06/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF42

341. USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics.

On April 17, 2008, FDA amended the IFR so that FDA may designate a country as not subject to certain BSE-related restrictions relating to prohibited cattle materials applicable to human food and cosmetics.

Comments submitted in response to the July 14, 2004 IFR that were not addressed in the September 7, 2005 and April 17, 2008 amendments will be addressed in the final rule. The final

rule also will respond to comments submitted following the September 7, 2005 and April 17, 2008 amendments.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Effective	07/14/04	
Interim Final Rule Comment Period End	10/12/04	
Interim Final Rule (Amendments)	09/07/05	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/05	
Interim Final Rule (Amendments) Comment Period End	11/07/05	
Interim Final Rule (Amendments)	04/17/08	73 FR 20785
Interim Final Rule (Amendments) Comment Period End	07/16/08	
Interim Final Rule (Amendments) Effective	07/16/08	
Final Action	10/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF47

342. OVER–THE–COUNTER (OTC) DRUG REVIEW—ACNE DRUG PRODUCTS CONTAINING BENZOYL PEROXIDE

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address acne drug products containing benzoyl peroxide.

Timetable:

Action	Date	FR Cite
Final Action	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG00

343. • REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

Regulatory Plan: This entry is Seq. No. 50 in part II of this issue of the **Federal Register**.

RIN: 0910–AG33

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Long-Term Actions

344. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

Legal Authority: 21 USC 321; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. FDA also published an Interim Final Rule in the same Federal Register (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	06/25/07	72 FR 34752
Interim Final Rule	06/25/07	72 FR 34959
Interim Final Rule Comment Period End	10/24/07	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AB88

345. OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC

drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes the monograph for emergency first aid eyewash drug products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/03	68 FR 7917
Final Action (Amendment) (Emergency First Aid Eyewashes)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF39

346. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM and final action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Timetable:

Action	Date	FR Cite
ANPRM (Plaque Gingivitis)	05/29/03	68 FR 32232
ANPRM Comment Period End	08/27/03	
NPRM (Plaque Gingivitis)	To Be	Determined
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF40

347. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	01/05/05	70 FR 741
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF51

348. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Timetable:

Action	Date	FR Cite
Final Action (Sodium Bicarbonate Labeling)	To Be	Determined
Final Action (Overindulgence Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF52

349. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching drug products containing hydroquinone.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51146

Action	Date	FR Cite
NPRM Comment Period End	12/27/06	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF53

350. OVER–THE–COUNTER (OTC) DRUG REVIEW—STIMULANT DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF56

351. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, ''UNITED STATES: REFUSED ENTRY.'' The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Timetable:

Action	Date	FR Cite
NPRM	09/18/08	73 FR 54106
NPRM Comment Period End	12/02/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF61

352. OVER–THE–COUNTER ANTIDIARRHEAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions address new labeling for antidiarrheal drug products.

Timetable:

Action	Date	FR Cite
NPRM (New Labeling)	To Be	Determined
Final Action (New Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF63

353. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses health care products. The second action addresses food handler products. The third action addresses testing requirements. The fourth action addresses consumer products. The final actions listed will address the healthcare, consumer, and first aid antiseptic drug products respectively.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare)	06/17/94	59 FR 31402
NPRM (Food Handlers)	To Be	Determined
NPRM (Testing)	To Be	Determined
NPRM (Consumer)	12/00/10	
Final Action (Healthcare)	To Be	Determined
Final Action (Consumer)	To Be	Determined
Final Action (First Aid Antiseptic)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF69

354. OVER–THE–COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF70

355. STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II ACTIVE INGREDIENTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This proposed rule is part of FDA's ongoing review of OTC drug products.

Timetable:

Action	Date	FR Cite
NPRM	06/19/08	73 FR 34895
NPRM Comment Period End	09/17/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF95

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) — Completed Actions

356. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; . . .

Abstract: Publication of this final rule was an action item in the Food Protection Plan announced by the Department of Health and Human Services (HHS) in November 2007.

In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of Salmonella Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses. The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. The proposal also solicited comment on whether recordkeeping requirements should include a written SE prevention plan and records for compliance with the SE prevention measures, and whether safe egg handling and preparation practices should be mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers). The proposed egg production SE prevention measures included: (1) Provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm. Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment

process that achieves at least a five-log destruction of SE.

The proposed rule was a step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons, and refrigerated storage of shell eggs at retail, and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA. The comment period was reopened until July 25, 2005, to solicit further comment and information on industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses.

On July 9, 2009, FDA published the final rule that requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA. FDA took this action because SE is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. The final rule will reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE.

Egg producers with 50,000 or more laying hens have 12 months to comply with the final rule, as do persons who must comply with only the refrigeration requirements. Producers with fewer than 50,000 but at least 3,000 laying hens have 36 months to comply. Producers with fewer than 3,000 laying hens and those who sell all of their eggs directly to consumers are exempt from the rule.

FDA is developing guidance documents and will hold public meetings this year to help ensure covered persons understand how to comply with the final rule.

Timetable:

Action	Date	FR Cite
NPRM	09/22/04	69 FR 56824
NPRM Comment Period End	12/21/04	
NPRM Reopened Comment Period End	06/09/05	70 FR 24490
NPRM Extension of Reopened Comment Period End	07/25/05	70 FR 33404
Final Action	07/09/09	74 FR 33030

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC14

357. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED TO PREVENT THE TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

Abstract: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to further strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking. On April 28, 2008, FDA published a final rule prohibiting the use of certain cattle origin materials in the food and feed of all animals. On October 23, 2008 FDA corrected the final rule on BSE that appeared in the Federal Register of April 25, 2008 (73 FR 22719-22758). The final rule was inadvertently published with incorrect dollar amounts in two separate areas: the summary of economic impacts and the paperwork burden table.

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	10/06/05	70 FR 58569
NPRM Comment Period End	12/20/05	
Final Rule	04/25/08	73 FR 22720
Final Rule–Correction	10/23/08	73 FR 63072
Final Rule Effective	04/27/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF46

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

358. ● REVISIONS TO THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS FOR CONTRACT YEAR 2011 (CMS–4085–F)

Legal Authority: MMA 2003; MIPPA (title XVIII of the Social Security Act)

Abstract: This proposed rule sets forth programmatic and operational changes to the Medicare Advantage and Prescription Drug Benefit programs (for example, strengthens beneficiary protections and sponsor entrance and exit rules, provides plan offerings with meaningful differences, improves payment rules and data collection for oversight and quality assessment).

Timetable:

Action	Date	FR Cite
NPRM	10/22/09	74 FR 54634

HHS—CMS

Proposed Rule Stage

Action	Date	FR Cite
NPRM Comment Period End	12/07/09	
Final Action	10/00/12	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP77

359. ● PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND FY 2011 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND RY 2011 RATES (CMS–1498–P)

Regulatory Plan: This entry is Seq. No. 53 in part II of this issue of the **Federal Register**.

RIN: 0938–AP80

360. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2011 (CMS–1504–P)

Regulatory Plan: This entry is Seq. No. 54 in part II of this issue of the **Federal Register**.

RIN: 0938–AP82

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

361. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CY 2010 (CMS–1413–FC)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Abstract: This rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B.

Timetable:

Action	Date	FR Cite
NPRM	07/13/09	74 FR 33520
NPRM Comment Period End	08/31/09	
Final Action	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP40

362. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2010 (CMS–1414–FC)

Legal Authority: BBA; BBA; BIPA; MMA; MMSEA; MIPPA; DRA; TRHCA

Abstract: This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, the rule describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also changes the Ambulatory Surgical Center Payment System list of services and rates. These changes applicable to services furnished on or after January 1 annually.

Timetable:

Action	Date	FR Cite
NPRM	07/20/09	74 FR 35231
NPRM Comment Period End	08/31/09	
Final Action	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP41

363. CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP); ALLOTMENT METHODOLOGY AND STATES' FISCAL YEAR 2009 CHIP ALLOTMENTS (CMS–2291–F)

Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) and 2104(f) of the Social Security Act; CHIPRA of 2009 (PL 111–3)

Abstract: This proposed rule describes the implementation of certain funding provisions under existing Medicaid laws, the Children's Health Insurance Program (CHIP) and recent legislation, and other related CHIP legislation. It proposes methodologies and procedures for determining States' fiscal year (FY) 2009 through FY 2013 allotments and payments

Timetable:

Action	Date	FR Cite
NPRM	09/16/09	74 FR 47517
NPRM Comment Period End	11/16/09	
Final Action	02/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP53

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

364. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

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RIN: 0938–AG81

365. ELECTRONIC CLAIMS ATTACHMENTS STANDARDS (CMS–0050–IFC)

Legal Authority: 42 USC 1320d–2(a)(2)(B)

Abstract: This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes.

Timetable:

Action	Date	FR Cite
NPRM	09/23/05	70 FR 55989
NPRM Comment Period End	11/22/05	
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AK62

366. HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–F) (SECTION 610 REVIEW)

Legal Authority: Deficit Reduction Act of 2005; PL 109–171, sec 6086

Abstract: This rule amends the Medicaid regulations to define and describe the home- and community-based State plan services implementing the new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

Timetable:

Action	Date	FR Cite
NPRM	04/04/08	73 FR 18676
NPRM Comment Period End	06/03/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO53

367. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This proposed rule would establish requirements that long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP32

368. STATE FLEXIBILITY FOR MEDICAID BENEFIT PACKAGES (CMS–2232–F4)

Legal Authority: PL 109–171, sec 6044

Abstract: This rule replaces the final rule published on December 3, 2008 (73 FR 73694) to implement provisions of the Deficit Reduction Act (DRA) of 2005. It also provides States increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid-eligible individuals. In addition, this final rule responds to public comments on the February 22, 2008 proposed rule as well as public comments on the December 3, 2009 ''final rule'' which was temporarily delayed twice, once by an interim final rule with comment period published on February 2, 2009, and the second time by a final rule published on April 3, 2009, further delaying the effective date and reopening the comment period.

Timetable:

Action	Date	FR Cite
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP72

Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS)

Completed Actions

369. MEDICAID GRADUATE MEDICAL EDUCATION (CMS–2279–F)

Legal Authority: title XIX; Social Security Act

Abstract: As part of the President's 2008 Budget, this rule establishes that States may not include GME as a reimbursable cost or program under their approved Medicaid State Plan. The rule enhances fiscal integrity and improves accountability with respect to payment for medical services in the Medicaid program.

Timetable:

Action	Date	FR Cite
NPRM	05/23/07	72 FR 28930
NPRM Comment Period End	06/22/07	
Withdrawn	10/08/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO95

370. GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (CMS–4137–IFC)

Legal Authority: Genetic information Nondiscrimination Act of 2008 (PL 110–223), enacted May 21, 2008.

Abstract: This rule implements statutory changes to the PHSA affecting the group and individual health insurance markets, non-federal governmental plans, and Medicare supplemental insurance (Medigap) made by the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-223).

Timetable:

Action	Date	FR Cite
ANPRM	10/10/08	73 FR 60208
ANPRM Comment Period End	12/09/08	
Interim Final Rule	10/07/09	74 FR 51663

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP37

371. CHANGES TO THE HOSPITAL INPATIENT AND LONG–TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2010 (CMS–1406–F)

Legal Authority: Sec 1886(d) of the Social Security Act

Abstract: This rule revises the Medicare hospital inpatient and Long Term Care prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	05/22/09	74 FR 24080
NPRM Comment Period End	06/30/09	
Final Rule	08/27/09	74 FR 43753

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP39

372. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2010 (CMS–1410–F)

Legal Authority: Social Security Act, sec 1888(e)

Abstract: This rule updates the payment rates used under the SNF PPS beginning October 1, 2009.

Timetable:

Action	Date	FR Cite
NPRM	05/12/09	74 FR 22208
NPRM Comment Period End	06/30/09	
Final Action	08/11/09	74 FR 40287

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP46

373. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM AND RATE UPDATE FOR CY 2010 (CMS–1560–F)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895; 42 USC 1395(fff)

Abstract: This rule updates the 60-day national episode rate and the national per visit rate amounts under the Medicare Prospective Payment System for home health agencies, effective January 1, 2010.

Timetable:

Action	Date	FR Cite
NPRM	08/06/09	74 FR 39435
NPRM Comment Period End	08/28/09	
Final Action	11/10/09	74 FR 58077
Final Action Effective	01/01/10	

HHS—CMS **Completed Actions**

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP55

374. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2010 (CMS–1538–F)

Legal Authority: Social Security Act, sec 1886(j); PL 106–554; PL 106–113

Abstract: This rule updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2010.

Timetable:

Action	Date	FR Cite
NPRM	05/06/09	74 FR 21052
Final Action	08/13/09	74 FR 40947
NPRM Comment Period End	06/29/09	

Regulatory Flexibility Analysis Required: Yes

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