Centers for Medicare and Medicaid Services, and is depended on to help manage the program. Being able to examine various characteristics and to chart evolving trends offers policy makers a reliable tool for making informed decisions. The MCBS is used to identify potential new policy direction or modifications to the Medicare program and once those program enhancements are implemented, monitor the impact of those changes. The central goals of the MCBS are to determine medical care expenditures and sources of payment for all services, including copayments, deductibles, and non-covered services; to ascertain all types of health insurance coverage and relate coverage to actual payments; and to trace processes over time, such as changes in health status, spending down to Medicaid eligibility, and the impacts of program changes. *Form Number:* CMS–P–0015A (OMB#: 0938–0568); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16,217 *Total Annual Responses:* 48,650; *Total Annual Hours:* 57,062 (For policy questions regarding this collection contact William Long at 410–786–7927. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Health Outcomes Survey (HOS); *Use:* CMS has a responsibility to its Medicare beneficiaries to require that care provided by managed care organizations under contract with CMS is of high quality. One way of ensuring high quality care in Medicare Managed Care Organizations (MCOs), or more commonly referred to as Medicare Advantage Organizations (MAOs), is through the development of standardized, uniform performance measures to enable CMS to gather the data needed to evaluate the care provided to Medicare beneficiaries.

The goal of the Medicare HOS program is to gather valid, reliable, clinically meaningful health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and improving health. All managed care plans with Medicare Advantage (MA) contracts must participate. CMS, in collaboration with the National Committee for Quality Assurance (NCQA), launched the Medicare HOS as part of the Effectiveness of Care component of the former Health Plan Employer Data and Information Set, now known as the Healthcare Effectiveness Data and Information Set (HEDIS®).

The HOS measure was developed under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. The measure includes the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techniques. In addition to health outcomes measures, the HOS is used to collect the Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management, and Osteoporosis Testing in Older Women HEDIS® measures. The collection of Medicare HOS is necessary to hold Medicare managed care contractors accountable for the quality of care they are delivering. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicare Advantage program. *Form Number:* CMS–10203 (OMB#: 0938–0701); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 1,099,560 *Total Annual Responses:* 1,099,560; *Total Annual Hours:* 366,520 (For policy questions regarding this collection contact Chris Haffer at 410–786–8764. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *September 13, 2010.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: August 6, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–19756 Filed 8–12–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0248]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 13, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content Requirements for Over-the-Counter Drug Product Labeling—OMB Control Number 0910–0340—Reinstatement

In the **Federal Register** of March 17, 1999 (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed over-the-counter (OTC) drug products in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings

and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

The only burden to comply with the regulations in part 201 is a one-time burden for the following products:

- New OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in "convenience size" packages[1]
- OTC sunscreen products.

The burden is limited to these products because, as explained in this document, most currently marketed OTC drug products are already required to be in compliance with these labeling regulations, and thus will incur no further burden in order to satisfy this regulation. We recognize that some manufacturers may choose to modify labeling already required to be in Drug Facts format. We believe that such changes are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the PRA. With the exceptions described, new products must comply with the regulations as they are introduced to the marketplace. Also, as explained in this document, OTC sunscreen products have not been required to comply with these regulations but are anticipated to become subject to these requirements when a sunscreen final rule becomes effective.

Specifically, on June 20, 2000 (65 FR 38191), we published a **Federal Register** document that required all OTC drug products marketed under the OTC monograph system except sunscreen products to comply with the regulations by May 16, 2005, or sooner (65 FR 38191 at 38193). Sunscreen products do not have to comply with the regulations until we lift the stay of the sunscreen final rule that was published in the **Federal Register** of May 21, 1999 (64 FR 27666) (the 1999 sunscreen final rule). In the **Federal Register** of December 31, 2001 (66 FR 67485), we stayed the 1999 sunscreen final rule indefinitely. In the **Federal Register** of September 3, 2004 (69 FR 53801), we delayed the § 201.66 implementation date for OTC sunscreen products indefinitely, pending future rulemaking to amend the substance of labeling for these products. In the **Federal Register** of August 27, 2007 (72 FR 49070), we proposed changes to labeling and related testing requirements for sunscreen products to address both ultraviolet A and ultraviolet B radiation, and anticipated that sunscreen products would become subject to § 201.66 at the time any resultant final rule becomes effective.

Based on a recent estimate provided by the Consumer Healthcare Products Association (CHPA),[2] we believe that approximately 900 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. Further, we estimate that these SKUs are marketed by 300 manufacturers. We estimate that the preparation of labeling for new OTC drug products will require 5 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 4,500 hours. (See table 1 of this document.)

We estimate that there are 4,752 OTC sunscreen drug product SKUs that have not yet complied with the 1999 labeling final rule. All of these SKUs will need to implement the new labeling format by the implementation date included in a sunscreen final rule when it is published in the **Federal Register**. We estimate that these 4,752 SKUs are marketed by 400 manufacturers and that approximately 2 hours will be spent on each submission. (See table 1 of this document.) The number of hours per submission (response) is based on our estimate in the 1999 labeling final rule (64 FR 13254 at 13276). If an average of 2 hours is spent preparing, completing, and reviewing each of the estimated 4,752 sunscreen SKUs, the total number of hours dedicated to the labeling of OTC sunscreen products would be 9,504 hours (4,752 SKUs times 2 hours/SKU). (See table 1 of this document.)

In determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). Since publication of the 1999 labeling final rule, we have received only one request for exemption or deferral. One response over an 8-year period equates to an annual frequency of response equal to 0.125. In the 1999 labeling final rule, we estimated that a request for deferral or exemption would require 24 hours to complete (64 FR 13254 at 13276). We continue to believe that this type of response will require approximately 24 hours. Multiplying the annual frequency of response (0.125) by the number of hour per response (24) gives a total response time for requesting exemption or deferral equal to 3 hours.

In the **Federal Register** of June 3, 2010 (75 FR 31448), we published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66(c) and (d)[2]	400	11.88	4,752	2	9,504
201.66(c) and (d)[3]	300	3	900	5	4,500
201.66(e)	1	0.125	0.125	24	3
Total					14,007

[1] We estimate that capital costs of 22 to 25 million dollars will result from preparing labeling content and format in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.

[1] In a final rule published in the **Federal Register** of April 5, 2002 (67 FR 16304), the agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (d)(9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The agency issued this delay in order to develop additional rulemaking for these "convenience size" products (December 12, 2006, 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.

[2] Letter submitted to FDA by CHPA on March 1, 2010 (available in Docket No. FDA–2010–N–0248).

[2] Burden for manufacturers of sunscreen drug products.
[3] Burden for manufacturers of new OTC drug products.

Dated: August 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19985 Filed 8–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0305]

John Bonnes: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring John Bonnes for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Bonnes was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Bonnes has notified FDA that he acquiesces to debarment, and therefore has waived his opportunity for a hearing concerning this action.

DATES: This order is effective April 19, 2010.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any food. Section 306(l)(1)(C) of the act (21 U.S.C. 335a(l)(1)(C)) provides that, for purposes of section 306, a person is considered to have been convicted of a criminal offense "when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld."

On April 17, 2010, Mr. Bonnes entered into a deferred prosecution agreement with the United States Attorney's Office, Eastern District of New York. FDA's finding that debarment is appropriate is based on the following facts, as set forth in the deferred prosecution agreement. Between April 1, 2006, and August 1, 2006, Mr. Bonnes did knowingly and willfully make materially false, fictitious, and fraudulent statements and representations, in a matter within the jurisdiction of the executive branch of the Government of the United States, in violation of 18 U.S.C. 1001(a)(2). Specifically, Mr. Bonnes' company, Ameritech Laboratories, provided seventeen certificates of analysis to a client certifying that fresh produce the client wished to import into the United States from the Dominican Republic was free of any pesticides. Mr. Bonnes signed each of the certificates of analysis as the director of Ameritech Laboratories.

Each of these certificates of analysis was false. Although the certificates stated that Ameritech Laboratories performed pesticide tests on the produce, Ameritech Laboratories did not perform a chemical analysis to certify that the produce was free of any pesticides. Mr. Bonnes knew at the time he prepared the certificates that they were false, and he also knew that the client intended to submit certificates to FDA's District Office in Queens, New York, in support of importing the produce into the United States for sale as human food.

Mr. Bonnes' actions and his deferred prosecution agreement make him subject to permissive debarment as described under section 306(b)(3)(A) of the act. Pursuant to the deferred prosecution agreement, Mr. Bonnes expressly acquiesced to permissive debarment under section 306(b)(1)(C) of the act for the conduct described in this document. In accordance with section 306(c)(2)(B) of the act (21 U.S.C. 335a(c)(2)(B)), Mr. Bonnes notified FDA of his acquiescence to debarment in a letter dated April 19, 2010. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act (21 U.S.C. 335a(i)), but by acquiescing to debarment Mr. Bonnes waived his opportunity for a hearing and to raise any contentions concerning his debarment. The maximum period of debarment under section 306(c)(2)(A)(iii) of the act (21 U.S.C. 335a(c)(2)(A)(iii)) is 5 years. FDA concludes that the nature and scope of Mr. Bonnes' conduct supports the maximum possible period of debarment.

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. John Bonnes has entered into a deferred prosecution agreement as the result of conduct relating to the importation of an article of food into the United States that makes him subject to permissive debarment.

As a result of the foregoing finding, Mr. Bonnes is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Under section 301(cc) of the act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Bonnes is a prohibited act.

Any application by Mr. Bonnes for termination of debarment under section 306(d)(1) of the act should be identified with Docket No. FDA–2010–N–0305 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–19981 Filed 8–12–10; 8:45 am]

BILLING CODE 4160–01–S