DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

1. Self-Evaluation and Recordkeeping Required by the Regulation Implementing Section 504 of the Rehabilitation Act of 1973 (45 CFR 84.6(c))—Extension—0990–0124—Recipients of DHHS funds must conduct a single-time evaluation of their policies and practices for compliance with Section 504 of the Rehabilitation Act of 1973. Recipients with fifteen or more employees must maintain records of their self-evaluation for three years. *Respondents:* State or local governments, businesses or other for-profit, non-profit institutions; *Annual Number of Respondents:* 2,120; *Frequency of Response:* once; *Burden per Response:* 16 hours; *Total Annual Burden:* 33,920 hours.

Send comments to Cynthia Agnes Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: December 15, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 01–133 Filed 1–2–01; 8:45 am]

BILLING CODE 4153–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Head Start Bureau; Advisory Committee on Head Start Research and Evaluation; Meeting

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Notice of meeting; Advisory Committee on Head Start Research and Evaluation.

SUMMARY: The 1998 Head Start Reauthorization (42 U.S.C. 9844(g); section 649(g)(1) of the Head Start Act, as amended) called on the Secretary of Health and Human Services to form an independent panel of experts (*i.e.,* an Advisory Committee) to offer advice concerning research designs that would provide a national analysis of the impact of Head Start Programs. The January 12, 2001 meeting provides an opportunity for the Advisory Committee to receive an update on the design and implementation plans for the study.

DATES: January 12, 2001, 8:30 a.m.–4 p.m.

PLACE: Hilton Washington Embassy Row, 2015 Massachusetts Avenue, NW., Washington, DC 20036. Telephone 202–265–1600. Fax: 202–328–7526.

SUPPLEMENTARY INFORMATION: This meeting is open to the public and is barrier free. Meeting records will also be open to the public and will be kept at the Switzer Building located at 330 C Street, SW., Washington, DC 20447. The Head Start Bureau also intends to make material related to this meeting available on the Head Start website (*http://www2.acf.dhhs.gov/programs/hsb/hsreac*). An interpreter for the deaf and hearing impaired will be available upon advance request by calling Ellsworth Associates at 703/821–3090 (ext. 282).

FOR FURTHER INFORMATION CONTACT: Michael L. Lopez, Ph.D. at 202–205–8212 for substantive information. ACF Office of Public Affairs at 202/401–9215 for press inquiries. Ellsworth Associates at 703/821–3090 (ext. 282) for logistical information.

Dated: December 27, 2000.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–80 Filed 1–2–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1666]

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the patent and exclusivity notification requirements under the new drug application (NDA) and abbreviated new drug application (ANDA) regulations.

DATES: Submit written or electronic comments on the collection of information by March 5, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions (OMB Control Number 0910–0305)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) requires patent owners to submit to FDA information about patents that cover approved drugs. Generic copies of these drugs may be approved when the patents expire or if a generic company certifies that the patent is invalid or will not be infringed. In such cases, the generic company must notify the patent owner about the certification, and approval of the drug may not be made effective until after the court decides the patent infringement suit or a period of 36 months, whichever occurs first. In addition, section 505 of the act provides several periods of marketing exclusivity ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases not receive) an ANDA for the drug product.

Under the authority found in sections 505 and 701 of the act (21 U.S.C. 371), FDA issued regulations governing patent and exclusivity provisions in 21 CFR part 314. The regulations provide instructions for NDA applicants (including section 505(b)(2) of the act applicants) and ANDA applicants on how to file patent information and request marketing exclusivity; require patent certification information for section 505(b)(2) applications and ANDA's; require information for requests for marketing exclusivity for NDA's (including section 505(b)(2) applications and certain NDA supplements); and require patent information for NDA's.

The specific reporting requirements that are the subject of this information collection are as follows:

21 CFR 314.50(i)—Requires the submission of patent certification information.

21 CFR 314.50(j)—Requires the submission of marketing exclusivity information.

21 CFR 314.52—Requires notice of certification of invalidity or noninfringement of a patent.

21 CFR 314.53—Requires the submission of patent information.

21 CFR 314.54(a)(1)(vii)—Requires the submission of marketing exclusivity information.

21 CFR 314.70(e)—Requires the submission of patent information.

21 CFR 314.70(f)—Requires the submission of marketing exclusivity information.

21 CFR 314.94(a)(12)—Requires the submission of patent certification information.

21 CFR 314.95—Requires notice of certification of invalidity or noninfringement of a patent.

21 CFR 314.107(c)(4), (e)(2)(iv), and (f)—Requires notice of the date of commercial marketing; a copy of the entry of the order or judgement; notice of the filing of legal action after notice of certification.

Applicants must provide information on patents to FDA to enable the agency to determine whether a product is covered by a patent or whether approval of a proposed drug product would result in patent infringement. The agency lists the patent information as a reference of potential applicants. If an applicant believes a patent is invalid or would not be infringed, Federal law also requires it to notify the patent holder. FDA approval, in such cases, is affected should there be any patent litigation. Failure to provide this information would result in an incomplete application and constitute grounds for refusing to approve the application.

Applicants submitting NDA's are required under the act to provide information on certain patents that cover their drug products. The agency lists this patent information in its publication entitled *List of Approved Drug Products With Therapeutic Equivalence Evaluations*.

To promote product innovation, the act also gives NDA applicants several periods of ''market exclusivity'' ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases, even receive) an ANDA for the drug product during that time period.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Number fo Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
PATENT INFORMATION					
314.50(h)					
314.53					
314.70(e)	85	3.8	325	2	650
PATENT CERTIFICATION INFORMATION					
314.50(i)					
314.94(a)(12)	97	3.4	331	2	662
NOTICE OF CERTIFICATION OF INVALIDITY OR NON-INFRINGEMENT OF A PATENT					
314.52					
314.95	37	2	75	16	1,200

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Number of Respondents	Number fo Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
MARKETING EXCLUSIVITY INFORMATION 314.50(j) 314.54(a)(1)(vii) 314.70(f)	92	2.7	250	2	500
NOTIFICATION OF DATE OF COMMERCIAL MARKETING; ENTRY OF THE ORDER OR JUDGEMENT; FILING OF LEGAL ACTION 314.107(c)(4),(e)(2)(iv),(f)(2), and (f)(3)	34	2	71	1	71
TOTAL					3,083

[1]There are no capital costs or operating and maintenance costs associated with this collection.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–45 Filed 1–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1505]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57192), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0450. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–46 Filed 1–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1489]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (Formerly Known and Approved Under Sterility Requirements for Inhalation Solution Products) (OMB Control Number 0910–0353)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by February 2, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (Formerly Known and Approved Under Sterility Requirements for Inhalation Solution Products) (OMB Control Number 0910–0353)

Sections 314.70(b) and 314.97 (21 CFR 314.70(b) and 314.97) require that all aqueous-based drug products for oral inhalation, including those currently approved, be manufactured sterile. Respondents will be required to submit a supplemental application under § 314.70(b) or § 314.97, describing their new manufacturing process for achieving sterility of their aqueous-based drug products for oral inhalation. FDA needs this information to determine compliance with this new regulation and will use information collected to make decisions on approval of supplemental applications.

Based on new information collected by its contractor, ERG, FDA has revised its estimate of the number of respondents in the original proposal for reporting and recordkeeping burden. Because the respondents have changed, the estimate of the total hours have changed. In the proposed rule it was estimated that there were 5 manufacturers, while the final rule estimates there are 8 manufacturers with 11 nonsterile products based on new data collected by ERG. However, four of the manufacturers are projected to cease manufacturing, leaving four companies manufacturing seven products. These companies are projected to cease manufacturing because they may lack