DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0487]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 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 comments on the collection of information by February 10, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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 listed below.

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; 21 CFR 314.50(i), 314.50(j), 314.52, 314.53, 314.54(a)(1)(vii), 314.70(f), 314.94(a)(12), 314.95, 314.107(c)(4), (e)(2)(iv), (f)(2), and (f)(3)—(OMB Control No. 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 part 314 (21 CFR part 314). The regulations provide instructions for NDA applicants (including section 505(b)(2) 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: (1) § 314.50(i) requires patent certification as part of a section 505(b)(2) application; (2) § 314.50(j) requires an NDA applicant to submit information if seeking marketing exclusivity; (3) § 314.52 requires section 505(b)(2) applicants to provide notice of certification of noninfringement of patent or invalidity to patent holders and NDA holders; (4) § 314.53 requires submission of patent information as part of an NDA or supplement; (5) § 314.54(a)(1)(vii) requires applicants to submit a statement if a section 505(b)(2) applicant is seeking marketing exclusivity for changes to a listed drug; (6) § 314.70(f) requires a statement if an applicant is seeking marketing exclusivity for a supplement; (7) § 314.94(a)(12) requires an applicant to submit patent information as part of an ANDA; (8) § 314.95 requires ANDA applicants to provide notice of certification of noninfringement of patent or invalidity to patent holders and NDA holders; and (9) §§ 314.107(c)(4), (e)(2)(iv), (f)(2), and (f)(3) require notice to FDA by ANDA or section 505(b)(2) application holders of any legal action concerning patent infringement.

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 for 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 titled ''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.

Respondents to this collection of information are new drug and abbreviated new drug applicants.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.50(i)	8	1	8	2	16
314.50(j)	50	1	50	2	100
314.52	8	1	8	8	64
314.53	200	1	200	1	200
314.54(a)(1)(vii)	8	1	8	1	8
314.70(f)	43	1	43	1	43
314.94(a)(12)	395	1	395	2	790
314.95	30	1	30	16	480
314.107(c)(4), (e)(2)(iv), (f)(2), (f)(3)	30	1	30	1	30
Total					1,731

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

This estimate is based on FDA's experience over the last 3 years in receiving this information, and the familiarity by FDA reviewers with the amount of time it takes to prepare and submit the information to FDA.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32553 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0320]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Filing Objections and Requests for a Hearing on a Regulation or Order'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1997 (62 FR 42257 to 42258), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0184. The approval expires on September 30, 2000.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32583 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0443]

Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' (compliance guide). This compliance guide is intended to help small entities comply with the final rule requiring label warnings and unit-dose packaging for iron-containing supplements and drug products. This action is being taken under the Small Business Regulatory Enforcement Fairness Act of 1996 (the SBREFA).

DATES: Written comments on the compliance guide may be submitted at any time.

ADDRESSES: An electronic version of the compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' is available on the Internet at ''http://vm.cfsan.fda.gov/~dms/secqiron.html''. Printed copies may be obtained from the Iron Labeling and Packaging, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Submit written comments on the compliance guide to the contact person below.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA issued a final rule requiring: (1) Label warning statements on products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes and (2) unit-dose packaging for iron-containing products that contain 30 milligrams or more of iron per dosage unit. This final rule became effective July 15, 1997.