DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0487]

Agency Information Collection Activities; Patent and Exclusivity Provisions; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by April 22, 1998.

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: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

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, and 314.107(c)(4), (e)(2)(iv), (f)(2), and (f)(3)—(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 abbreviated new drug application (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 new drug application (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: (1) Section 314.50(i) requires patent certification as part of a section 505(b)(2) of the act 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; (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 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.

In the **Federal Register** of December 12, 1997 (62 FR 65431), the agency requested comments on the proposed collection of information. No comments were received.

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

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

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
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), and (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: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7474 Filed 3–20–98; 8:45 am]

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

Year 1998 and 2000 Continuation of National Surveys of Prescription Drug Information Provided to Patients—(OMB Control Number 0910–0279—Reinstatement)

FDA implements the provisions of the Federal Food, Drug, and Cosmetic Act (the act), designed to assure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular, and under section 201(n) of the act (21 U.S.C. 321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts. FDA also has the authority to collect this information under Title VI of Pub. L. 104–180 (Related Agencies and Food and Drug Administration) section 601 (Effective Medication Guides), which directs the development of ''a mechanism to assess periodically * * * the frequency with which the [oral and written prescription] information is provided to consumers.''

To assure that Rx drugs are not misbranded, FDA has historically asserted that adequate labeling requires certain information be provided to patients. In 1982, when FDA revoked a planned initiative to require mandatory patient package inserts for all Rx drugs in favor of private sector initiatives in this area, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. Surveys of consumers about their receipt of Rx drug information were carried out in 1982, 1984, 1992, 1994, and 1996. This notice is in regard to continuing the survey in years 1998 and 2000.

The survey is conducted by telephone on a national random sample of adults age 18 and over who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which oral and written information was received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are also obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this information, the agency would be unable to assure that adequate Rx labeling and information is provided.

Respondents to this collection of information are adults (18 years or older), in the continental United States who have obtained one or more new (nonrefill) prescriptions at a pharmacy for themselves or a member of their household in the last 4 weeks.

In the **Federal Register** of December 11, 1997 (62 FR 65273), the agency invited comments on the collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN: SCREENER[1]

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1998	11,044	1	11,044	.03	331
1999	0	0	0	0	0
2000	11,044	1	11,044	.03	331
Annual average	7,363		7,363		221

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