

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 00N-1666]

Agency Information Collection Activities; Submission for OMB Review; 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 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 (PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

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.

Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions (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 as 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:

- § 314.50(i)—Requires the submission of patent certification information
- § 314.50(j)—Requires the submission of marketing exclusivity information
- § 314.52—Requires notice of certification of invalidity or noninfringement of a patent
- § 314.53—Requires the submission of patent information

- § 314.54(a)(1)(vii)—Requires the submission of marketing exclusivity information
- § 314.70(e)—Requires the submission of patent information
- § 314.70(f)—Requires the submission of marketing exclusivity information
- § 314.94(a)(12)—Requires the submission of patent certification information
- § 314.95—Requires notice of certification of invalidity or noninfringement of a patent
- § 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*, which is available on the Internet at <http://www.fda.gov/cder/ob>.

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 January 3, 2001 (66 FR 372), the agency requested comments on the proposed collections of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents per Response	Annual Frequency per Response	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 noninfringement of a patent. 314.52. 314.95	37	2	75	16	1,200
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 of information.

Dated: 3/29/01
March 29, 2001.

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William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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