Orphan Drugs—(21 CFR Part 316)—(OMB Control Number 0910–0167—Reinstatement)

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give the FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

FDA estimates 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
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total					20,964

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 5 years, that 90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (21 CFR 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–10 Filed 1–2–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0512]

Agency Information Collection Activities; 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 February 4, 1998.

ADDRESSES: Submit written comments on the collection of information to 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: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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:

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses—21 CFR

801.410(c), (e), and (f)—(OMB Control Number 0910–0182)—Reinstatement

FDA has the statutory authority under section 501, 502, and 371(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, and 371(a)) to regulate medical devices. Section 801.410 (21 CFR 801.410) requires that lenses be rendered impact-resistant and capable of withstanding the impact test referred to as the ''referee test'' in the regulation. Under § 801.410(c)(1), eyeglasses and sunglasses must be fitted with impact-resistant lenses except in cases where an optometrist or physician finds that such lenses will not fulfill a patient's visual requirements. In such cases, the optometrist or physician must notify the patient in writing and specify in a written prescription that nonimpact lenses be used in the patient's eyewear.

Under § 801.410(e) and (f), manufacturers and distributors of impact-resistant lenses, both eyeglasses and sunglasses, are required to maintain certain records. Under § 801.410(e) manufacturers, distributors, retailers, and importers are required to maintain records such as invoice(s), shipping documents, and records of sale or distribution of all impact-resistant lenses, including finished prescription eyeglasses and sunglasses, which shall be kept and maintained for a period of 3 years. However, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. Under § 801.410(f) any persons conducting ''referee'' (lens impact) tests in accordance with § 801.410(d) shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years.

These records are valuable to FDA when investigating complaints (i.e., eye injury complaints). If records were not maintained, FDA investigations would be made more difficult to conduct and ultimately the public would not have the necessary protection from substandard eyeglasses. The regulation is designed to protect the eyeglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses. Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer. Between 50 and 60 percent of the American public wear prescription eye wear.

Firms subject to this regulation are not required to submit the written records to FDA. FDA normally reviews and may copy records during an inspection of the manufacturer. The manufacturers are required to make the records available to FDA on an ''as needed'' basis.

Respondents to this collection of information are manufacturers, importers, distributors, and retailers of impact-resistant sunglasses and eyeglasses.

The burden of maintaining sale and/or distribution records, as required by § 801.410(e), is estimated at 0 hours because firms are routinely retaining the records beyond the 3-year period for reasons of routine business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the recordkeeping needed to comply is usual and customary because it would occur in the normal course of activities. Based on conversations with eye care professionals, FDA also estimates that the burden under § 801.410 is virtually nil because very few prescriptions for nonimpact lenses are written. Therefore, no estimate for this section has been included in the chart.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	590,000	17,700,000	492	14,760

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

There are approximately 30 manufacturers of eyeglasses in the U.S. Optical Manufacturers Association, which represents 98 percent of the domestic industry involved in lens manufacturing, and the association has stated to FDA that the regulation does not impose a burden on their members. This position is based on the fact that the recordkeeping and testing requirements of the regulation represent minimum requirements for a conscientious manufacturer.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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