[1] In accordance with 45 CFR 96.85, each State's estimated median income for a 4-person family is multiplied by the following percentages to adjust for family size: 52% for one person, 68% for two persons, 84% for three persons, 100% for four persons, 116% for five persons, and 132% for six persons. For family sizes greater than six persons, add 3% for each additional family member and multiply the new percentage by the State's estimated median income for a 4-person family.

[2] Prepared by the Bureau of the Census from the March 1999 Current Population Survey, 1990 Decennial Census of Population and Housing, and 1998 per capita personal income estimates, by state, from the Bureau of Economic Analysis (BEA). In 1999, BEA revised its methodology in estimating per capita personal income estimates. BEA's revised methodology is reflected in the FY 2002 state 4-person family median income estimates. For further information, contact the Housing and Household Economic Statistics Division at the Bureau of the Census (301–457–3242).

[FR Doc. 01–5536 Filed 3–6–01; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1599]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

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 April 6, 2001.

ADDRESSES: Submit written comment 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: Peggy 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 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 (OMB Control Number 0910–0182)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), every manufacturer or importer of a device intended for human use shall establish and maintain records. This regulation is designed to protect the eyeglass and sunglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses, and it requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. The regulation in § 801.410(f) (21 CFR 801.410(f)) requires that the results of impact tests and description of the test method and apparatus also be kept for a period of 3 years. These records are valuable to FDA when investigating eye injury complaints.

The expected respondents to this collection are manufacturers of impact-resistant lenses.

In the **Federal Register** of November 28, 2000 (65 FR 70916), the agency requested comments on the proposed collection of information. One comment was received. The comment stated the estimate seems to include only the time for testing, but omitted the cost of the materials and their disposal. It stated that the estimate did not explicitly address whether this testing is destructive in nature. These costs are material.

FDA's attempt at addressing these issues was limited by the Vision Council of America's (VCA) reluctance to provide any more information than what had been included in FDA's original submission. VCA informed FDA that there was a restriction on information because VCA had promised their clients that they would not release certain data that was considered critical. Because of this limited amount of information from FDA's most reliable source (VCA), FDA was limited to the estimated burden that was included in the original submission (OMB control number 0910–0182).

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,000	.0008	19,225

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to an inadvertent error, the recordkeeping burden hours for § 801.410(f) that appeared in a notice issued in the FEDERAL REGISTER of November 28, 2000, were incorrect. Table 1 of this document contains the correct estimates.

VCA provided sales figures (www.visionsite.org) that were used in estimating the burden for this collection. Beginning in 1998, a growth rate of 2.6 percent for the distribution of lenses began, and it was assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by year 2000.

By also assuming that the glass/plastic lenses-produced ratio remained as in previous years (22 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent of the remaining plastic lenses (5 percent x 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. Previously, FDA and industry experts estimated that on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete 1,200 tests per hour. Therefore, it is estimated that the total burden for this collection is 19,225 hours, which is calculated by taking the total records figure (23,070,000) and dividing it by tests per hour (1,200). The total hours was calculated by multiplying the total number of records

(23,070,000) and the hours per record (.0008).

There is no burden estimated for maintaining sale or distribution records under § 801.410(e) because firms are retaining their records as a normal and customary business practice for reasons of product liability.

Dated: March 1, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–5472 Filed 3–6–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1235]

Determination of Regulatory Review Period for Purposes of Patent Extension; Aciphex™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Aciphex™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Aciphex™ (rabeprazole sodium). Aciphex™ is indicated for healing of erosive or ulcerative gastroesophageal reflux disease (GERD), maintenance of healing of erosive or ulcerative GERD, healing of duodenal ulcer, and treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aciphex™ (U.S. Patent No. 5,045,552) from Eisai Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 12, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aciphex™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Aciphex™ is 2,922 days. Of this time, 2,415 days occurred during the testing phase of the regulatory review period, while 507 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: August 21, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: March 31, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Aciphex™ (NDA 20–973) was initially submitted on March 31, 1998.

3. *The date the application was approved*: August 19, 1999. FDA has verified the applicant's claim that NDA 20–973 was approved on August 19, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,713 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by May 7, 2001. Furthermore, any interested person may petition for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 4, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–5513 Filed 3–6–01; 8:45 am]

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