utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on frequency of use.

FDA estimates the burden of the Cosmetic Product Voluntary Reporting Program as follows:

ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | Form No. | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Burden Hours |
|---|---|---|---|---|---|---|
| 720.1 & 720.4 (new submissions) | FDA 2512/2512a | 550 | 4.2 | 2,310 | 0.50 | 1,155 |
| 720.4 & 720.6 (amendments) | FDA 2512/2512a | 550 | 1.4 | 770 | 0.33 | 254 |
| 720.6 (notice of discontinuance) | FDA 2514 | 550 | 4.5 | 2,500 | 0.1 | 250 |
| 720.8 (request for confidentiality) | | 2 | 1.0 | 2 | 1.5 | 3 |
| Total | | | | | | 1,662 |

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

This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: August 21, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–22121 Filed 8–28–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96N–0261]**

## Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

**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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the submission of reclassification petitions for medical devices.

**DATES:** Submit written comments on the collection of information by October 28, 1996.

**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:** Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 reinstatement 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.

### Reclassification Petitions for Medical Devices—21 CFR Part 860 (OMB Control Number 0910–0138)

*Type of OMB Approval Requested:* Reinstatement Without Change of a Previously Approved Collection for Which Approval has Expired

FDA has the responsibility under sections 513(e), 513(f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and 21 CFR part 860, subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a medical device from

any one of three classes (I, II, III) to another class. The reclassification procedures regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting downclassification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

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

ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 860.123 | 11 | 1 | 11 | 500 | 5,500 |

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

Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: August 21, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–22122 Filed 8–28–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96E–0113]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; VEXOL™

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VEXOL™ 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:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 VEXOL™ (rimexolone). VEXOL™ is indicated for the treatment of postoperative inflammation following ocular surgery and in the treatment of anterior uveitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VEXOL™ (U.S. Patent No. 4,686,214) from Alcon Laboratories, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 13, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VEXOL™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VEXOL™ is 1,779 days. Of this time, 1,566 days occurred during the testing phase of the regulatory review period, while 213 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: February 17, 1990. FDA has verified the applicant's claim that the date that the investigation new drug application (IND) became effective was on February 17, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: June 1, 1994. The applicant claims May 31, 1994, as the date the new drug application (NDA) for VEXOL™ (NDA 20–474) was initially submitted. However, FDA records indicate that NDA 20–474 was submitted on June 1, 1994.

3. *The date the application was approved*: December 30, 1994. FDA has verified the applicant's claim that NDA 20–474 was approved on December 30, 1994.