Both SBREFA and the Presidential Memorandum exclude violations that pose serious environmental threats from the penalty reduction policy. Because FDA's enforcement efforts generally focus on actions that affect the public health and safety, but not the environment, the condition is not included in the draft penalty reduction policy. If a small entity is eligible for CMP reduction, but has obtained an economic benefit from the violations such that it may have obtained an economic advantage over its competitors, FDA may seek the full amount of the penalty. FDA retains this discretion to ensure that small entities that comply with public health laws enforced by the agency are not disadvantaged by those who have not complied.

FDA has determined that all CMP's assessed under the authority of the Generic Drug Enforcement Act (GDEA) should be excluded from the draft penalty reduction policy. Under GDEA, CMP's may be assessed for a variety of intentional or ''knowing'' conduct related to abbreviated new drug applications (21 U.S.C. 335b(a)). Also, GDEA permits CMP's for debarred individuals who provide services in any capacity to persons who have approved or pending drug product applications (id). Because of the level of scientist required to assess a CMP under GDEA, FDA believes it is not appropriate to consider reduction or waiver of penalties in such cases.

The National Childhood Vaccine Injury Act (NCVIA) also has a provision for CMP, for which intentional or knowing conduct is a requirement for assessment of penalties. Section 2128(b) of the Public Health Service Act (42 U.S.C. 300aa–28) states that a CMP may be assessed when a vaccine manufacturer intentionally destroys, alters, falsifies, or conceals records associated with the manufacture of vaccines. Accordingly, FDA believes it is not appropriate to consider reduction or waiver of CMP in cases involving this provision of the NCVIA.

Definition of ''Small Entity''

Section 211(1) of SBREFA defines the term ''small entity'' as having the same meaning as in section 601 of the United States Code (5 U.S.C. 601). Section 601 defines ''small entity'' as ''small business,'' ''small organization'' and ''small governmental jurisdiction.''

Under section 601(3) of 5 U.S.C., a ''small business'' has the same meaning as ''small business concern'' under section 3 of the Small Business Act (15 U.S.C. 632(a)), unless an agency, after consultation with the Office of Advocacy of the Small Business Administration (SBA) and after opportunity for public comment, establishes its own definition.

Section 632(a)(1) of 15 U.S.C. defines a ''small business concern'' as an enterprise ''which is independently owned and operated and which is not dominant in its field of operation'' (15 U.S.C. 632(a)(1)). The SBA has further defined ''small business concern'' for a number of specific industries based on the sizes of the enterprises and their affiliations (see 13 CFR part 121 and the SBA Table of Size Standards).

When SBA determines whether an enterprise is a small business, it generally counts the enterprise's affiliations (see 13 CFR 121.103). Family enterprises or enterprises in which the same individual or individuals have a controlling interest are aggregated for this purpose. If the aggregate total of the affiliated enterprises exceeds the size requirement for small businesses, none of the affiliated enterprises is considered a small business.

Federal law defines ''small organization'' as a not-for-profit enterprise which is independently owned and operated and not dominant in its field (5 U.S.C. 601(4)). The U.S. Code defines a ''small governmental jurisdiction'' as a governmental entity with a population of less than 50,000 (5 U.S.C. 601(5)). The definitions of ''small organization'' and ''small governmental jurisdiction'' may be changed by agencies after an opportunity for public comment. The small business definitions within the nutritional food labeling exemptions (21 CFR 101.9(j) and 101.36(h)) are not applicable to CMP's.

III. Regulatory Requirements

FDA is announcing a draft penalty reduction policy as required by SBREFA. As a general statement of policy, the Administrative Procedure Act does not require that FDA publish this draft policy for notice and comment. However, under the Good Guidance Practices published in the **Federal Register** of February 27, 1997 (62 FR 8961), FDA is providing interested parties, particularly small entities, with an opportunity to comment on the draft penalty reduction policy. This draft policy is being issued for public comment only and will not be implemented until a final policy is published in the **Federal Register**.

This guidance document represents the agency's current thinking on the draft CMP reduction policy for small entities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

IV. Request for Comments

Interested persons may, on or before August 16, 1999, submit to the Dockets Management Branch (address above) written comments on the document entitled ''Draft Civil Money Penalty Reduction Policy for Small Entities.'' Two copies of any comments 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. Although all received comments will be considered by FDA in formulating the final penalty reduction policy, the agency is not obligated to respond to each comment. The agency will make changes to the draft penalty reduction policy, as appropriate. Copies of the draft policy and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

A copy of the draft policy may also be downloaded to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs (ORA) home page includes the draft policy and may be accessed at ''http://www.fda.gov/ora''. The draft policy will be available under ''Compliance References.''

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12390 Filed 5–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0789]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lotemax™ and Alrex™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lotemax™ and Alrex™ 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Lotemax™ and Alrex™ (loteprednol etabonate). Lotemax™ is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, conrnea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selective infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable dimunition in edema and inflammation. Alrex™ is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lotemax™ and Alrex™ (U.S. Patent No. 4,996,335) from Nicholas S. Bodor, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lotemax™ and Alrex™ 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 Lotemax™ and Alrex™ is 3,092 days. Of this time, 2,017 days occurred during the testing phase of the regulatory review period, while 1,075 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:* September 22, 1989. The applicant claims January 2, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 22, 1989, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* March 31, 1995. The applicant claims March 29, 1995, as the date the new drug application (NDA) for Lotemax™ and Alrex™ (NDA 20–583) was initially submitted. However, FDA records indicate that NDA 20–583 was submitted on March 31, 1995.

3. *The date the application was approved:* March 9, 1998. FDA has verified the applicant's claim that NDA 20–583 was approved on March 9, 1998.

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 1,284 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 15, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12392 Filed 5–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Subcommittee of the Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Subcommittee of the Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 3, 1999, 8:30 a.m. to 6 p.m., and June 4, 1999, 8 a.m. to 3 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71),