research team to accomplish proposed activities. The extent to which the research team includes expertise in genital herpes research, behavioral and social sciences, health services research, health economics, epidemiology, biostatistics, and laboratory sciences as appropriate for the proposed project.

h. The degree of commitment and cooperation of proposed collaborators and participating organizations, as evidenced by letters detailing the nature and extent of the involvement.

i. Capacity to carry out the project, including adequacy of existing and proposed facilities and resources.

j. Inclusion of Women and Racial and Ethnic Minorities in Research: The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

k. Human subjects: The extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects.

l. The reasonableness of the proposed budget to the proposed research.

2. The second review will be conducted by a secondary review committee of Senior Federal officials. The factors to be considered will include:

a. The results of the peer review.

b. Geographic distribution.

c. The overall match between the proposal and the program interests.

d. Overall balance among the four major areas of interest: (1) the behavioral and psycho social impact and indirect and intangible costs of genital herpes infections; (2) acceptability of screening for genital HSV; (3) correlates of infectivity among asymptomatic and symptomatic infected persons; and (4) relative risk of HSV transmission from asymptomatic and symptomatic infected persons to sex partners.

e. Budgetary considerations.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports semiannually;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialists identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7—Executive Order 12372 Review
AR–9—Paperwork Reduction Act
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2000
AR–12—Lobbying Restrictions

J. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 318 of the Public Health Service Act, [42 U.S.C. 247c], as amended. The Catalog of Federal Domestic Assistance number is 93.978.

K. Where To Obtain Additional Information

This and other CDC announcements may be downloaded from the CDC Internet home page—http://www.cdc.gov. Click on ''funding.''

To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99115, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770)488–2716, E-mail address: spo2@cdc.gov

For program technical assistance, contact: Katherine Stone, Division of STD Prevention, Centers for Disease Control and Prevention (CDC), Mail Stop E–02, 1600 Clifton Road, Atlanta, Georgia 30333, Telephone (404) 639–8183; FAX (404) 639–8610, E-mail address: kms1@cdc.gov

Dated: May 12, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–12438 Filed 5–17–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1220]

Draft Civil Money Penalty Reduction Policy for Small Entities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a draft civil money penalty reduction policy for small entities as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995. 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**.

DATES: Written comments on the draft policy may be submitted by August 16, 1999.

ADDRESSES: Submit written comments on the draft policy to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft policy.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is issuing a draft civil money penalty (CMP) reduction policy for small entities (draft penalty reduction policy) as mandated by SBREFA (Pub. L. 104–121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies as follows:

Sec. 223—Rights of Small Entities in Enforcement Actions

(a) In General—Each agency regulating the activities of small entities shall establish a policy * * * to provide for the reduction, and under appropriate circumstances for the waiver, of civil penalties for violations of a statutory or regulatory requirement by a

small entity. Under appropriate circumstances, an agency may consider ability to pay in determining penalty assessments on small businesses.

(b) Conditions and Exclusions—Subject to the requirements or limitations of other statutes, policies or programs established in this section shall contain conditions or exclusions which may include, but not be limited to—

(1) requiring the small entity to correct the violation within a reasonable correction period;

(2) limiting the applicability to violations discovered through participation by the small entity in a compliance assistance or audit program operated or supported by the agency or a State;

(3) excluding small entities that have been subject to multiple enforcement actions by the agency;

(4) excluding violations involving willful or criminal conduct;

(5) excluding violations that pose serious health, safety or environmental threats; and

(6) requiring a good faith effort to comply with the law.

A statement entered into the Congressional Record (142 Congressional Record S3242, daily ed. March 29, 1996) after enactment of SBREFA explains that agencies have ''flexibility to tailor their specific programs to their missions and charters'' and instructs agencies ''to develop the boundaries of their program and the specific circumstances for providing for a waiver or reduction of penalties'' (id. at S3244). To that end, SBREFA specifies that a penalty reduction policy adopted by an agency may be subject to the requirements or limitations of other applicable statutes. SBREFA also lists six possible exclusions or conditions (see section 223 of SBREFA as quoted previously in this document) that an agency may incorporate in its policy.

This draft penalty reduction policy also complies with the Presidential Memorandum of April 21, 1995, which directs agencies to implement the policy of waiving penalties as follows:

1. *Authority to Waive Penalties.* (a) To the extent permitted by law, each agency shall use its discretion to modify the penalties for small businesses in the following situations. Agencies shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time period appropriate to the violation in question. For those violations that may take longer to correct than the period set by the agency, the agency shall use its enforcement discretion to waive up to 100 percent of the financial penalties if the amounts waived are used to bring the entity into compliance. The provisions in paragraph 1(a) of this memorandum shall apply only where there has been a good faith effort to comply with applicable regulations and the violation does not involve criminal wrongdoing or significant threat to health, safety, or the environment.

FDA has reviewed: (1) The Federal statutes it enforces which authorize CMP's, (2) its current practices used to assess CMP's on small entities, and (3) the appropriate conditions and exclusions for a penalty reduction policy for small entities that violate the law. On the basis of that review, FDA announces its draft penalty reduction policy for small entities. FDA invites comments on this draft policy.

FDA currently enforces the following amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C.) and the Public Health Service Act (42 U.S.C.), which authorize CMP's under the referenced sections:

Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 360pp),

Safe Medical Devices Act of 1990 (21 U.S.C. 333(f)),

Mammography Quality Standards Act of 1992 (42 U.S.C. 263b(h)),

National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 262(d)(2) and 42 U.S.C. 300aa–28),

Prescription Drug Marketing Act of 1988 (21 U.S.C. 333(b)),

Generic Drug Enforcement Act of 1992 (21 U.S.C. 335b), and

Food Quality Protection Act of 1996 (21 U.S.C. 333(f)).

II. Draft Civil Money Penalty Reduction Policy for Small Entities

The FDA's draft policy with respect to reducing or waiving civil money penalties (CMP's) against a small entity is: FDA will consider on a case-by-case basis whether to reduce or waive CMP's against a small entity. In determining whether to reduce or waive CMP's against a specific small entity, the following considerations will apply:

A. Except as provided in paragraph C below, penalty reduction or waiver will not be available for any small entity if:

1. The small entity was subject to an enforcement action (e.g. seizure, injunction or prosecution) by FDA within the last 5 years, and is still under the same management;

2. Any of the small entity's violations involved willful conduct;

3. The small entity does not make a good faith effort to comply with the law; or

4. Any of the small entity's violations pose serious health or safety threats.

B. In considering whether FDA will reduce or waive a CMP, FDA may consider:

1. The egregiousness of the violations;

2. The isolated or repeated nature of the violations;

3. The small entity's history (if any) of violations;

4. The amount of harm caused by the violations;

5. The degree to which a CMP will deter the small entity or others from committing future violations;

6. The extent to which the small entity cooperated during the investigation;

7. Whether the small entity corrected the violations within a reasonable time period;

8. Whether the small entity has engaged in subsequent significant remedial efforts to mitigate the effects of the violations and to prevent future violations;

9. Whether the small entity voluntarily reported the violations to FDA promptly after discovering them; and

10. The small entity's efforts to determine and meet its legal obligations.

C. FDA may also consider whether to reduce or waive a CMP against a small entity, including a small entity otherwise excluded from this draft policy under paragraph A above, if the small entity can demonstrate to the FDA's satisfaction that it is financially unable to pay the penalty, immediately or over a reasonable period of time, in whole or in part.

D. If a small entity corrects the violative conditions within a reasonable time period, FDA may reduce the amount of any CMP that may be imposed for the violations, up to the amount spent by the small entity for corrective action. FDA may take into account the time in which the small entity took corrective action and any difficulties the small entity encountered when doing so.

Penalties Eligible for Reduction

The draft penalty reduction policy will apply to judicial and administrative CMP's.

Exclusions From the Draft Penalty Reduction Policy

The draft penalty reduction policy shall not apply to any remedy that may be sought by FDA other than CMP's.

SBREFA also permits an agency to apply penalty reduction to violations discovered through a small entity's participation in a compliance assistance or audit program operated or supported by the agency or state. Although various units within FDA provide regulatory guidance to small entities, FDA does not operate a formal compliance assistance or audit program. Because FDA does not have a compliance program of the type described in SBREFA, this condition is not included in the draft penalty reduction policy.

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