

Commissioner of Food and Drugs under 21 CFR 5.10) to request that the Commissioner of Food and Drugs ____ (issue, amend, or revoke a regulation or amend or revoke an order that the agency has issued or published or take an action as specifically provided by regulation).

A. Action requested

((1) If the petition requests that the Commissioner issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests that the Commissioner amend or revoke an order, the date on which the order was issued or published, the exact wording and the citation for the existing order and, if the request is to amend an order, the exact wording requested for the amended order.)

((3) If the petition requests that the Commissioner take an action, and a petition is specifically required by regulation, a citation of the regulation and the specific action requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position. Additionally, for petitions requesting that FDA issue, amend, or revoke a regulation, the petition shall show why the requested regulation pertains to a subject that is appropriately addressed by regulation rather than other administrative action. For petitions requesting that FDA amend or revoke an order that was issued or published, the petition shall be based on more than unsupported claims, allegations, or general descriptions of positions or arguments.

C. Environmental impact

(A claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of the requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, that it is well grounded in fact and is warranted by existing laws or regulations, that it is not submitted for any improper purpose, such as to harass or to cause unnecessary delay, and that it includes representative data and information

known to the petitioner which are unfavorable to the petition.

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2) of this section, act upon each petition filed under paragraph (c) of this section, taking into consideration:

(i) Available agency resources for the category of subject matter;

(ii) The priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency; and

(iii) Time requirements established by statute.

(2) Except as provided in paragraphs (e)(4) and (e)(5) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition; or

(ii) Deny the petition; the denial may be brief, as appropriate; or

(4) The Commissioner may:

(i) Refer a petition for other administrative action instead of issuing a response. In such cases, the agency shall place a note in the docket for the petition stating that the petition has been referred for other administrative action and close the docket for the petition. FDA may refer a petition for other administrative action if the petition:

(A) Involves issues that are the subject of an ongoing or future administrative proceeding. In such cases, the agency may consider the issues raised by the petition as part of the administrative record for the administrative proceeding;

(B) Presents scientific or technical issues or data that are specific to a particular product or class of products;

(C) Requests a regulation on an issue that is not appropriately addressed by regulation;

(D) Does not involve a significant public health or consumer protection issue; or

(E) Involves a subject that is appropriately addressed by other administrative action.

(F) For petitions described in paragraphs (e)(4)(i)(B) through (e)(4)(i)(E) of this section, the agency may treat the petition as correspondence under § 10.65.

(ii) Request clarification if the petition presents vague or conflicting requests. If the petitioner does not respond to the request for clarification within a time

specified by FDA, the petition may be considered withdrawn;

(iii) Consider the petition to be withdrawn if the petitioner no longer exists or cannot be located or the petitioner has stated that it does not seek a response from the agency; or

(iv) Combine petitions and supplements submitted by the same petitioner or by different petitioners if those petitions concern the same or similar subjects or products.

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Dated: August 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

RIN 1076-AD90

Acquisition of Title to Land in Trust

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; Reopening of comment period.

SUMMARY: This notice reopens the comment period for submission of electronic access and filing of comments only for the proposed rule published at 64 FR 17574-17588, April 12, 1999, Acquisition of Title to Land in Trust. Due to circumstances beyond our control, a malfunction in the computer system prevented receipt of comments via the Internet after August 1, 1999. Comments submitted via the Internet between August 1, 1999 and November 12, 1999 were not received. Please resubmit your Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include "Attn: 1076-AD90" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact the Office of Trust Responsibilities directly at (202) 208-5831.

DATES: Comments must be received on or before December 29, 1999.

ADDRESSES: Please resubmit your e-mail comments to: landcomments@bia.gov.

FOR FURTHER INFORMATION CONTACT:

Terry Virden, Director, Office of Trust Responsibilities, Bureau of Indian Affairs, MS-4513, Main Interior Building, 1849 C Street, NW,

Washington, DC 20240; by telephone at (202) 208-5831; or by telefax at (202) 219-1065.

SUPPLEMENTARY INFORMATION: On Monday, April 12, 1999, the Bureau of Indian Affairs published a proposed rule, 64 FR 17574-17588, concerning the Acquisition of title to land in trust. The deadline for receipt of comments was July 12, 1999, which was extended to October 12, 1999 and extended again to November 12, 1999. The comment period is extended for an additional thirty days to allow additional time for receipt of e-mail comments on the proposed rule. Intranet comments must be received on or before December 29, 1999.

Dated: November 23, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA72-7206C; A-1-FRL-6481-1]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Enhanced Motor Vehicle Inspection and Maintenance Program and Rate of Progress Emission Reduction Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplementary proposed rule.

SUMMARY: The EPA is providing additional information and reopening the comment period for two notices of proposed rulemaking to approve State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts. These documents were published in the **Federal Register** on September 27, 1999. The first is a rulemaking action proposing approval of the Massachusetts motor vehicle inspection and maintenance (I/M) program (64 FR 51937), and the second is a rulemaking action proposing approval of the Massachusetts rate-of-progress plans for reducing the emissions of ozone precursors in the Springfield ozone nonattainment area (64 FR 51943). This document reopens the comment period on both of these rules and provides additional information on the I/M test to be used in Massachusetts and the timing of 15% and 9% rate-of-progress plan reductions. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before December 30, 1999. Public comments on this document are requested and will be considered before taking final action on this SIP revision.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, One Congress Street, Suite 1100, Boston, MA 02114-2023. Copies of Massachusetts' submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA; and the Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Peter Hagerty, (617) 918-1049.

SUPPLEMENTARY INFORMATION: On March 27, 1997, the Commonwealth of Massachusetts submitted an inspection and maintenance plan under the provisions on the National Highway Systems Designation Act. On July 14, 1997, EPA published in the **Federal Register** (62 FR 37506) an Interim Final Rule conditionally approving the Commonwealth's I/M SIP. The notice conditioned approval on start-up of the program by November 15, 1997, which was based on a commitment made by the Commonwealth as part of the SIP submittal. That **Federal Register** notice also listed other elements of the I/M program for which the Commonwealth was required to submit additional information. By means of a November 14, 1997, letter, EPA notified Massachusetts that EPA was converting the conditional approval of the enhanced I/M SIP revision to a disapproval on November 15, 1997 due to the fact that the program was not starting on November 15, 1997. The letter triggered the 18-month time clock for the mandatory application of sanctions under section 179(a) of the CAA. Therefore, the Act's offset sanction applied beginning May 15, 1999 because Massachusetts still had no enhanced I/M program started or approved as part of its SIP.

I. Enhanced I/M SIP

In order to remedy the failure to start its enhanced I/M program in November 1997, Massachusetts submitted a revision to its SIP on May 14, 1999 for an enhanced I/M program to begin on October 1, 1999. The Commonwealth in fact commenced operation of the

program on October 1, 1999. Although the Commonwealth commenced operation of the I/M program on October 1, 1999, there were routine start-up difficulties which required that DEP temper full enforcement of the program for two and one half months. During October, November and early December 1999, the Commonwealth is allowing drivers to obtain temporary stickers approving cars to operate for a year if a station in the program did not have fully operational test equipment ready when a driver came in for a test. In a November 15, 1999 letter to EPA, the Commonwealth has indicated that such temporary stickers will not be available starting December 15, 1999, and any car that must get tested will be required to find a station with operable testing equipment. This step ensures that the I/M program will meet EPA's definition of start-up and that the Commonwealth is fully enforcing an approvable I/M program as of December 15, 1999.

In the September 27, 1999 proposed approval of the I/M program (64 FR 51937), there were other elements of the I/M SIP which needed to be addressed prior to final action by EPA. These elements will be addressed by the contractor the Commonwealth has retained to implement the program and are listed as work elements of the contractor's scope of services. Since the focus of the contractor and the Commonwealth has been program start-up, these elements have not been addressed by the contractor to date. In response to EPA's September 27, 1999 proposed approval which describes the program elements Massachusetts must supplement, the Commonwealth submitted in a letter dated November 3, 1999 a schedule for submitting these elements from January to March 2000. As stated before, a November 15, 1999 letter informed EPA that the Commonwealth has taken steps that ensure the I/M program will be fully enforced starting December 15, 1999. Additional information submitted in support of the Commonwealth's I/M program is included in the contract with Keating Technologies signed January 28, 1999, Department of Environmental Protection (DEP) Regulations, chapter 310 CMR 60.02, and Registry of Motor Vehicles Regulations, chapter 540 CMR 4.00-4.09, and administrative items, including a description of the program being implemented and DEP's response to comments document dated May 14, 1999.

Starting on October 1, 1999, the Commonwealth began implementing a 31 second transient test utilizing the BAR 31 trace and NYTEST equipment. In the September 27, 1999 proposed