4. Part 358 is amended by adding new subpart D, consisting of § § 358.301 to 358.350, to read as follows:

Subpart D—Ingrown Toenail Relief Drug Products

Sec.
358.301 Scope.
358.303 Definitions.
358.310 Ingrown toenail relief active ingredient.
358.350 Labeling of ingrown toenail relief drug products.

Subpart D—Ingrown Toenail Relief Drug Products

§ 358.301 Scope.

(a) An over-the-counter ingrown toenail relief drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.303 Definitions.

As used in this subpart:

(a) *Ingrown toenail relief drug product.* A drug product applied to an ingrown toenail that relieves pain or discomfort either by softening the nail or by hardening the nail bed.

(b) *Retainer ring.* A die cut polyethylene foam pad coated on one side with medical grade acrylic pressure-sensitive adhesive. The retainer ring has slots, center-cut completely through the foam with the cut of sufficient size to allow for localization of an active ingredient in a gel vehicle to a specific target area. The retainer ring is used with adhesive bandage strips to place over the retainer ring to hold it in place.

§ 358.310 Ingrown toenail relief active ingredient.

The active ingredient of the product is sodium sulfide 1 percent in a gel vehicle. The gel vehicle is an aqueous, semisolid system with large organic molecules interpenetrated with a liquid.

§ 358.350 Labeling of ingrown toenail relief drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the product, if any, and identifies the product as an ''ingrown toenail relief product'' or as an ''ingrown toenail discomfort reliever.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''for temporary relief of'' [select one or both of the following: 'pain' or 'discomfort'] ''from ingrown toenails''. Other truthful and nonmisleading statements, describing only the use that has been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''For external use only'' in accord with § 201.66(c)(5)(i) of this chapter.

(2) ''Do not use [bullet][1] on open sores''.

(3) ''Ask a doctor before use if you have [bullet] diabetes [bullet] poor circulation [bullet] gout''.

(4) ''When using this product [bullet] use with a retainer ring''.

(5) ''Stop use and ask a doctor if [bullet] redness or swelling of your toe increases [bullet] discharge is present around the nail [bullet] symptoms last more than 7 days or clear up and occur again within a few days''.

(d) *Directions.*The labeling of the product contains the following statements under the heading ''Directions'':

(1) ''[Bullet] adults and children 12 years and over:''

(i) ''[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the area where the ingrown nail and the skin meet. Smooth ring down firmly. [bullet] apply enough gel product to fill the slot in the ring [bullet] place round center section of bandage strip directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toes.''

(ii) ''[Bullet] repeat twice daily (morning and night) for up to 7 days until discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed''.

(2) ''[Bullet] children under 12 years: ask a doctor''.

Dated: September 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25251 Filed 10–3–02; 8:45 am]

BILLING CODE 4160–01–S

[1]See § 201.66(b)(4) of this chapter for definition of bullet.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–083–7213b; A–1–FRL–7375–1]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Volatile Organic Compound Reasonably Available Control Technology (RACT) Plans and Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve several State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts. These revisions establish reasonably available control technology (RACT) requirements for major volatile organic compound (VOC) sources. The intended effect of this action is to approve these requirements into the Massachusetts SIP. EPA is taking this action in accordance with the Clean Air Act (CAA).

DATES: Written comments must be received on or before November 4, 2002.

ADDRESSES: Comments may be mailed to David Conroy, Unit Manager, Air Quality Planning, Office of Ecosystem Protection (mail code CAQ), U.S. Environmental Protection Agency, EPA New England Regional Office, 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, EPA New England Regional Office, One Congress Street, 11th floor, Boston, MA and Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Anne Arnold, (617) 918–1047.

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving Massachusetts' SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If EPA receives no relevant adverse comments in response to this rule, we contemplate no further activity. If EPA receives relevant adverse comments, we will

withdraw the direct final rule and will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: September 3, 2002.

Robert W. Varney,

Regional Administrator, EPA New England.

[FR Doc. 02–25159 Filed 10–3–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[MA–075–7209b; A–1–FRL–7374–8]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Approval of PM10 State Implementation Plan (SIP) Revisions and Designation of Areas for Air Quality Planning Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Massachusetts. This revision replaces the standard for Total Suspended Particulates (TSP) with a standard for particulate matter with a mean aerodynamic diameter of 10 microns or less (PM10) as the National Ambient Air Quality Standard (NAAQS) for particulates. EPA also proposes to redesignate several areas of Massachusetts from ''nonattainment'' for TSP to ''cannot be classified.'' In the Final Rules Section of this **Federal Register**, EPA is approving Massachusetts's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If EPA receives no adverse comments in response to this action, the Agency contemplates no further activity. If EPA receives relevant adverse comments, the Agency will withdraw the direct final rule, and will address all public comments received in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before November 4, 2002.

ADDRESSES: Comments may be mailed to Steven Rapp, Manager, Air Permits Program Unit (mail code CAP), U.S. Environmental Protection Agency, EPA-New England, One Congress Street, Suite 1100, Boston, MA 02114–2023. Copies of the 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, EPA-New England, 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: Ian D. Cohen, (617) 918–1655.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: August 29, 2002.

Robert W. Varney,

Regional Administrator.

[FR Doc. 02–25155 Filed 10–3–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[I.D. 092602H]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

AGENCY: Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS).

ACTION: Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

SUMMARY: The Administrator, Northeast Region, NMFS (Regional Administrator) has made a preliminary determination that the subject EFP application contains all the required information and warrants further consideration. The Regional Administrator has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of the Northeast (NE) Multispecies Fishery Management Plan (FMP). However, further review and consultation may be necessary before a final determination is made to issue the EFP. Therefore, NMFS announces that the Regional Administrator proposes to issue an EFP that would allow one vessel to conduct fishing operations that are otherwise restricted by the regulations governing the fisheries of the Northeastern United States. The experiment proposes to conduct a study of an experimental bycatch reduction device in order to develop otter trawl gear for the NE multispecies fishery that would result in reduced catch of Atlantic cod. The EFP would allow these exemptions for one commercial vessel, for not more than 5 days of sea trials. All experimental work would be monitored by Manomet Center for Conservation Sciences personnel.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

DATES: Comments on this document must be received on or before October 21, 2002.

ADDRESSES: Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Manomet EFP Proposal for Rigid Mesh Bycatch Reduction Device.'' Comments may also be sent via facsimile (fax) to 978–281–9135.

FOR FURTHER INFORMATION CONTACT: Tom Warren, Fishery Policy Analyst, 978–281–9347.

SUPPLEMENTARY INFORMATION: An application for an EFP was submitted by Manomet Center for Conservation Sciences on August 19, 2002.

The EFP would allow for exemptions from the Gulf of Maine (GOM) Regulated Mesh Area gear requirements at 50 CFR 648.80(a)(3)(i) and the days-at-sea (DAS) requirements at § 648.82(a).