of a United States Court of Appeals on an issue, we may decide under certain conditions to relitigate that issue within the same circuit. We may relitigate only when the conditions specified in paragraphs (c)(2) and (3) of this section are met, and, in general, one of the events specified in paragraph (c)(1) of this section occurs.

(1) Activating events:

(i) An action by both Houses of Congress indicates that a circuit court decision on which an Acquiescence Ruling was based was decided inconsistently with congressional intent, such as may be expressed in a joint resolution, an appropriations restriction, or enactment of legislation which affects a closely analogous body of law;

(ii) A statement in a majority opinion of the same circuit indicates that the court might no longer follow its previous decision if a particular issue were presented again;

(iii) Subsequent circuit court precedent in other circuits supports our interpretation of the Social Security Act or regulations on the issue(s) in question; or

(iv) A subsequent Supreme Court decision presents a reasonable legal basis for questioning a circuit court holding upon which we base an Acquiescence Ruling.

(2) The General Counsel of the Social Security Administration, after consulting with the Department of Justice, concurs that relitigation of an issue and application of our interpretation of the Social Security Act or regulations to selected claims in the administrative review process within the circuit would be appropriate.

(3) We publish a notice in the **Federal Register** that we intend to relitigate an Acquiescence Ruling issue and that we will apply our interpretation of the Social Security Act or regulations within the circuit to claims in the administrative review process selected for relitigation. The notice will explain why we made this decision.

(d) *Notice of relitigation.* When we decide to relitigate an issue, we will provide a notice explaining our action to all affected claimants. In adjudicating claims subject to relitigation, decisionmakers throughout the SSA administrative review process will apply our interpretation of the Social Security Act and regulations, but will also state in written determinations or decisions how the claims would have been decided under the circuit standard. Claims not subject to relitigation will continue to be decided under the Acquiescence Ruling in accordance with the circuit standard. So that affected claimants can be readily identified and any subsequent decision of the circuit court or the Supreme Court can be implemented quickly and efficiently, we will maintain a listing of all claimants who receive this notice and will provide them with the relief ordered by the court.

(e) *Rescission of an Acquiescence Ruling.* We will rescind as obsolete an Acquiescence Ruling and apply our interpretation of the Social Security Act or regulations by publishing a notice in the **Federal Register** when any of the following events occurs:

(1) The Supreme Court overrules or limits a circuit court holding that was the basis of an Acquiescence Ruling;

(2) A circuit court overrules or limits itself on an issue that was the basis of an Acquiescence Ruling;

(3) A Federal law is enacted that removes the basis for the holding in a decision of a circuit court that was the subject of an Acquiescence Ruling; or

(4) We subsequently clarify, modify or revoke the regulation or ruling that was the subject of a circuit court holding that we determined conflicts with our interpretation of the Social Security Act or regulations, or we subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.

[FR Doc. 98–11945 Filed 5–5–98; 8:45 am]

BILLING CODE 4190–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; interpretation.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it does not intend to apply to combination products currently regulated under human drug or biologic labeling provisions its September 30, 1997, final rule requiring certain labeling statements for all medical devices that contain or have packaging that contains natural rubber that contacts humans. FDA is taking this action, in part, in response to a citizen petition and other communications from industry that the agency has received since the publication of the final rule. FDA intends to initiate a proceeding to propose natural rubber labeling requirements for drugs and biologics, including combination products that are currently regulated under drug and biologic labeling provisions. Such a proceeding may include a combination of rulemaking and guidance and will offer opportunity for public comment.

EFFECTIVE DATE: September 30, 1998.

FOR FURTHER INFORMATION CONTACT:

Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0737.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA published a final rule to be codified at 21 CFR 801.437 requiring certain labeling statements on medical devices that contain or have packaging that contains natural rubber that contacts humans. The labeling statements alert users that a product contains either dry natural rubber or natural rubber latex, and for products containing natural rubber latex that the presence of this material may cause allergic reactions. The final rule, which becomes effective September 30, 1998, was adopted because natural rubber may cause a significant health risk to persons who are sensitized to natural latex proteins.

In response to a comment on the proposed latex labeling regulation (61 FR 32618, June 24, 1996) about the applicability of the requirements to combination products, FDA stated in the preamble to the final rule that it intended to require combination products (i.e., drug/device and biologic/device combinations) that contain natural rubber device components to be labeled in accordance with § 801.437 (62 FR 51021 at 51026). Because the entities that comprise a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to such products, as specified in the Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health and the Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and

Radiological Health (the Intercenter Agreements).

Concerning the implementation of the final rule for these combination products, the FDA stated that natural rubber combination products that are listed in the Intercenter Agreements as being regulated under device labeling provisions will be required to comply with the final rule on the effective date. FDA stated that natural rubber combination products that are listed in the Intercenter Agreements as being regulated under drug or biologic labeling provisions will be subject to the labeling requirements on September 30, 1998, or when FDA amends the Intercenter Agreements to provide that these types of combination products are subject to the requirements, whichever is later. FDA stated that it would provide notice in the **Federal Register** of the amendments to the Intercenter Agreements to apply the labeling requirements to all natural rubber combination products regulated under drug and biologic provisions. FDA also stated then that: ''the agency anticipates that the Drug/Device Intercenter Agreement will be amended to reflect that prefilled drug vial containers, transdermal patches, infusion pumps, and prefilled syringes that presently are regulated under drug authorities are also subject to this regulation'' (62 FR 51021 at 51026).

The agency has received numerous inquiries about, and objections to, the application of the natural rubber labeling requirements to combination drug/device products and to combination biologic/device products that currently are regulated under drug and biologic labeling provisions. These include a citizen petition submitted by the Health Industry Manufacturers Association (Docket No. 98P–0012/CP1). One concern was that some combination products may raise different labeling issues than single-entity device products. In addition, a concern was raised that adequate notice and opportunity for comment was not provided with regard to the applicability of the rule to combination products that currently are regulated under drug and biologic labeling provisions.

FDA believes that the notice provided was legally sufficient. However, upon consideration of these comments and the need to provide a uniform labeling approach for all drug and biological products, including combination products currently regulated under drug and biologic labeling provisions, FDA has decided that further opportunity for public comment should be provided on how natural rubber labeling requirements should be applied to all products regulated as drugs and biologics. FDA believes that it would benefit from additional public comment on whether there are labeling issues that are unique to products regulated as drugs and biologics as well as on whether the agency should adopt rules and guidance that would apply to all natural rubber-containing products regulated under the drug and biologic labeling provisions rather than only to combination products.

Therefore, FDA is announcing that it does not intend to amend the Intercenter Agreements as stated in the preamble to the final rule. Instead, FDA intends to initiate a proceeding to propose requirements for labeling statements on products regulated as drugs and biologics, including combination products currently regulated under drug and biologic labeling provisions, that contain natural rubber that contacts humans. Such a proceeding may include a combination of proposed rulemaking and guidance and will offer opportunity for public comment. In the interim, FDA is providing notice that it does not intend to apply to combination products regulated under human drug or biologic labeling provisions its September 30, 1997, final rule requiring certain labeling statements for all medical devices that contain or have packaging containing natural rubber that contacts humans.

Dated: April 30, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–11982 Filed 5–5–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OR–67–7282, OR–70–7285; FRL–5976–5]

Approval and Promulgation of State Implementation Plans: Oregon

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Pursuant to procedures described in the January 19, 1989 **Federal Register**, EPA recently approved two minor State Implementation Plan (SIP) revisions submitted by the Oregon Department of Environmental Quality (ODEQ). These revisions include: changes to the definition of Volatile Organic Compounds (VOC) in the Oregon Administrative Rules (OAR) consistent with changes made in the federal definition and delisting certain compounds no longer considered VOCs; and, changes in the OAR that increase Air Contaminant Discharge Permit Fees for stationary sources to recover costs of operating the state permit program. This document lists the revisions EPA has approved and incorporates the relevant material into the Code of Federal Regulations.

EFFECTIVE DATE: June 5, 1998.

ADDRESSES: Copies of Oregon's State SIP revision requests and EPA's letter notices of approval are available for public inspection during normal business hours at the following locations: EPA, Region 10, Office of Air Quality (OAQ–107), 1200 Sixth Avenue, Seattle, Washington 98101; State of Oregon Department of Environmental Quality, 811 SW Sixth Ave., Portland, OR 97204–1390.

FOR FURTHER INFORMATION CONTACT: Tracy Oliver, Office of Air Quality (OAQ–107), EPA, Seattle, Washington, (206) 553–1388.

SUPPLEMENTARY INFORMATION: EPA Region 10 has approved the following minor SIP revision requests under section 100(a) of the Clean Air Act (Act):

State	Subject matter	Date of submission	Date of approval
OR	Changes to the definition of VOC in the OAR consistent with changes in the federal definition. Delisting perchloroethylene, acetone, HFC 43–10mee and HCFC 225ca and cb which are no longer considered VOCs.	5–22–97	6–16–97
OR	Changes in the OAR that increase the Air Contaminate Permit Fees for stationary sources and allow the state to recover the costs of operating the permit program.	11–13–97	2–13–98