concentration established in § 347.10 may be combined with one or more skin protectant active ingredients identified in § 347.10(a), (d), (e), (f), (h), (i), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.

(2) Two or more sunscreen active ingredients when used in the concentrations established in § 352.20(a)(3) may be combined with one or more skin protectant active ingredients identified in § 347.10(a), (d), (e), (f), (h), (i), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.

* * * * *

4. Section 352.52 is amended by adding a new paragraph (b)(2)(vi) and by revising the headings of paragraphs (b)(3), (c)(2), (d)(3) and (e)(5) to read as follows:

§ 352.52 Labeling of sunscreen drug products.

* * * * *

(b) * * *

(2) * * *

(vi) *For products containing the active ingredient identified in § 352.10(b), the following labeling statements may be used*—(A) ''Broad spectrum sunscreen.''

(B) ''Provides'' (select one of the following: ''UVB and UVA'' or ''broad spectrum'') ''protection.''

(C) ''Protects from UVB and UVA'' (select one of the following: ''Rays'' or ''radiation'').

(D) (Select one of the following: ''Absorbs,'' ''Protects,'' ''Screens,'' or ''Shields'') ''throughout the UVA spectrum.''

(E) ''Provides protection from the UVA rays that may contribute to skin damage and premature aging of the skin.''

(3) *For products containing the active ingredient identified in § 352.10(t) that provide an SPF of 12 to 30, the following labeling statement may be used.* * * *

(c) * * *

(2) *For products containing the ingredient identified in § 352.10(j)*— * * *

* * * * *

(d) * * *

(3) *For products containing the ingredient identified in § 352.10(j).* * * *

* * * * *

(e) * * *

(5) *For products containing the active ingredient identified in § 352.10(t) that provide an SPF of 12 to 30, the following labeling statement may be used.* * * *

* * * * *

Dated: September 5, 1995.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23547 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–152P]

Schedules of Controlled Substances: Proposed Placement of Remifentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the deputy Administrator of the Drug Enforcement Administration (DEA) to place the narcotic drug, remifentanil and salts thereof, into Schedule II of the Controlled Substances Act (CSA). The Deputy Administrator has received a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) that remifentanil, and salts thereof, be added to Schedule II. This rule, if finalized, would require that the manufacture, distribution, dispensing, security, registration, record keeping, inventory, exportation and importation of remifentanil, and salts thereof, be subject to the CSA regulatory control mechanisms and criminal sanctions applicable to Schedule II narcotic substances.

DATES: Comments, objections and requests for a hearing must be submitted on or before October 16, 1996.

ADDRESSES: Comments, objections and requests for a hearing should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537; Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Acting Chief, Drug and Chemical Evaluation Section, 202–307–7183.

SUPPLEMENTARY INFORMATION: The Deputy Administrator of the DEA received a letter dated August 23, 1996, from the Assistant Secretary for Health, on behalf of the Secretary of the DHHS, recommending that the substance, remifentanil, and salts thereof, be placed into Schedule II of the CSA (21 U.S.C. 801 et seq.). Remifentanil hydrochloride, a short-acting, potent μ-opioid, was approved recently by the Food and Drug Administration (FDA) for marketing as an intravenous analgesic agent for use during the induction and maintenance of general anesthesia and monitored anesthesia care.

Enclosed with the letter from the Assistant Secretary was a document prepared by the FDA entitled ''Basis for the Recommendation for Controlling Remifentanil and its Salts in Schedule II of the Controlled Substances Act.'' The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(b)] and the summarized recommendations regarding the placement of remifentanil into Schedule II of the CSA.

The factors considered by the Assistant Secretary for Health with respect to the drug remifentanil were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect;

(3) The state of current scientific knowledge regarding the drug;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary of Health, received in accordance with section 201(f) of the Act [21 U.S.C. 811(f)], the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act [21 U.S.C. 811(a) and 811(b)], finds that:

(1) Based on information now available, remifentanil has a high potential for abuse;

(2) Remifentanil has a currently accepted medical use in treatment in the United States; and

(3) Abuse of remifentanil may lead to severe psychological or physical dependence.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be

submitted to the Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537. Attention: DEA Federal Register Representative. In the that comments, objections, or requests for a hearing raise one or more issues which the Deputy Administrator finds warrants a hearing, the Deputy Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action is a formal rule making ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1).

The Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Remifentanil is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule II of the CSA. Remifentanil, a potent opioid drug, can produce drug dependence of the morphine type. This drug is likely to be diverted and abused if access to it is not closely monitored. The labeled indication for use of remifentanil is to provide analgesia during the induction and maintenance of general anesthesia. It is to be administered by trained professionals in monitored anesthesia care settings. Schedule II narcotic control will provide the necessary drug monitoring. Small-business entities which are likely to handle this drug maintain a Schedule II narcotic registration with the DEA. This proposed rule, if finalized, will allow these entities to have access to a new pharmaceutical product.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, drug traffic control, narcotics, prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

§ 1308.12 [Amended]

2. Section 1308.12 would be amended by redesignating the existing paragraph (c)(26) as (c)(27) and adding a new paragraph (c)(26) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(26) Remifentanil 9739

* * * * *

Dated: September 9, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96–23557 Filed 9–13–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[PS–29–95]

RIN 1545–AT60

Available Unit Rule; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations concerning the low-income housing credit.

DATES: The public hearing originally scheduled for September 17, 1996, beginning at 10:00 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Christina Vasquez of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–6808 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 42 of the Internal Revenue Code. A notice of proposed rulemaking and notice of public hearing appearing in the Federal Register for Thursday, May 30, 1996 (61 FR 27036), announced that a public hearing on the proposed regulations would be held on Tuesday, September 17, 1996, beginning at 10:00 a.m., room 2615, 1111 Constitution Avenue NW. Washington, DC.

The public hearing scheduled for Tuesday, September 17, 1996, is cancelled.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 96–23569 Filed 9–11–96; 4:54 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[VA041–5005b; FRL–5603–6]

Approval and Promulgation of Air Quality Implementation Plans; Virginia Emission Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revisions submitted by the Commonwealth of Virginia for the purpose of establishing 1990 ozone base year emission inventories for the Virginia ozone nonattainment areas. In the Final Rules section of this Federal Register, EPA is approving the Commonwealth's SIP revisions as a direct final rule without prior proposal because the Agency views them as noncontroversial SIP revisions and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.