

basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning June 26, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1310 is added to read as follows:

§ 520.1310 Marbofloxacin tablets.

(a) *Specifications.* Each tablet contains either 25, 50, 100, or 200 milligrams of marbofloxacin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 1.25 milligrams per pound of body weight once daily, but may be increased to 2.5 milligrams per pound of body weight once daily.

(ii) *Indications for use.* For the treatment of infections in dogs associated with bacteria susceptible to marbofloxacin.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

Dated: July 15, 1999.

George A. Mitchell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 99-18769 Filed 7-22-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

United States Mint

31 CFR Part 100

RIN 1525-ZA00

Exchange of Coin

AGENCY: United States Mint, Treasury.

ACTION: Final rule.

SUMMARY: In furtherance of the U.S. Mint's efforts to improve the environment, reduce energy consumption and enhance workplace safety and efficiency, the Mint wishes to discontinue melting and instead employ mechanical means to destroy mutilated coins. These mechanical means cannot be used to process fused or mixed coins, which represent a very small percentage of the coins redeemed annually by the Mint. Accordingly, by this amendment the Mint will also discontinue accepting fused or mixed coins for redemption, and require that all bent or partial coins submitted for redemption be separated by denomination in order to be acceptable.

EFFECTIVE DATE: August 23, 1999.

FOR FURTHER INFORMATION CONTACT:

(Legal) Gwen Mattleman, Attorney-Advisor (202) 874-4043, or Kenneth Gubin, Chief Counsel (202) 874-5953; (Technical) Andrew Cosgarea, Associate Director, Head, Circulating Coinage Business Unit (202) 874-6100.

SUPPLEMENTARY INFORMATION:

Background

Part 100, Subpart C of Treasury Regulations 31 CFR, promulgated under 31 U.S.C. 5120, provides for the exchange of bent, partial, fused and mixed coins. The Mint has identified and is actively pursuing initiatives to improve the environment, reduce energy consumption and enhance efficiency and workplace safety. Melting coins submitted for redemption by the

Mint's current heat induction procedures is not energy efficient and adds to the Mint's annual electrical expenses. It is also a physically challenging process for the Mint's employees. For these reasons, in 64 FR 4063, January 27, 1999, the Mint published a proposed rule notifying the public of its intention to discontinue melting and begin using mechanical means (such as a hammer mill or rolling mill) to destroy mutilated coins. As the mechanical destruction process requires that coins be separated by alloy, these mechanical methods cannot be used to process fused coins or unsorted (mixed) coin lots. Mutilated coins delivered in these lots of mixed alloy categories often are in a condition which precludes machine sorting, and redemption of mixed coins can be labor-intensive and inefficient. Fused and mixed coins represent a very small component of the United States Mint's annual coin redemptions. Therefore, the Mint's proposed rule published in 64 FR 4063, January 27, 1999 also notified the public of the Mint's intention to amend Part 100 of 31 CFR to discontinue acceptance of fused and mixed coins for redemption and require that all bent or partial coins submitted for redemption be separated by denomination. Comments were solicited through the January 27, 1999 publication of the proposed rule in the **Federal Register** (which included telephone numbers of legal and technical staff and a dedicated email address). No comments from the public were received. For the foregoing reasons, effective 30 days from the date of publication of this final rule, the Mint amends Part 100 of 31 CFR to discontinue acceptance of fused and mixed coins for redemption and to require that all bent or partial coins submitted for redemption be separated by denomination.

Special Analyses

This regulation is not a significant regulatory action for purposes of Executive Order 12866. The Mint has paid out less than \$8 million in total annual mutilated coin redemptions for each of 1996, 1997 and the seven-month period ending July 31, 1998. For each such period, fused and mixed coins as a group constitute less than 1% of total coins redeemed, and approximately 1% or less of the total lots redeemed. Fused and mixed coins are currently redeemed at metal rates lower than the rates paid for sorted coins. For these reasons, the United States Mint does not believe that the regulation will have an annual effect on the economy of \$100 million or more or materially adversely affect any sector of the economy, productivity,

competition, jobs, the environment, public health, or State, local, or tribal governments or communities. The Mint does not anticipate that the rule will result in inconsistency, interfere with another agency's actions, materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. It is hereby certified that this regulation will not have a significant economic impact on a significant number of small entities. Accordingly, a regulatory flexibility analysis is not required. Lots of fused and mixed coins recorded together as a group constituted approximately 1% or less of the total coin lots redeemed for each of calendar 1996, 1997 and the period ending July 31, 1998, amounting to 23, 19 and 13 lots, respectively, of fused and mixed coins. Although the Mint does not maintain records which consistently indicate the business or personal nature of the transactions conducted by individuals or entities tendering coins for redemption, the majority of these lots were submitted by individuals transacting with the Mint in their own name. Even if each such individual were a "small entity" within the meaning of 5 U.S.C. 604(a), the Mint does not believe that this quantity of lots indicates that a significant number of small entities will be significantly impacted if the Mint were to require sorting of coins previously accepted as mixed and discontinue accepting fused coins.

List of Subjects in 31 CFR Part 100

Currency, Gold.

For the reasons set forth in the preamble, the United States Mint amends 31 CFR Part 100 as follows:

PART 100—EXCHANGE OF PAPER CURRENCY AND COIN

Subpart C—Exchange Of Coin

1. The authority citation for Part 100 is revised to read as follows:

Authority: 31 U.S.C. 321.

2. Revise § 100.11(b) to read as follows:

§ 100.11 Exchange of bent and partial coins.

(b) *Redemption basis.* Bent and partial coins shall be presented separately by denomination category in lots of at least one pound for each category. Bent and partial coins shall be redeemed on the

basis of their weight and denomination category rates (which is the weight equivalent of face value). If not presented separately by denomination category, bent and partial coins will not be accepted for redemption. Denomination categories and rates are Cents, @ \$1.4585 per pound; Nickels, @ \$4.5359 per pound; Dimes, Quarters, Halves, and Eisenhower Dollars @ \$20.00 per pound; and Anthony Dollars @ \$56.00 per pound. Copper plated zinc cents shall be redeemed at the face value equivalent of copper one cent coins.

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3. Revise § 100.12(b) to read as follows:

§ 100.12 Exchange of fused and mixed coins.

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(b) The United States Mint will not accept fused or mixed coins for redemption.

Philip N. Diehl,

Director.

[FR Doc. 99-18849 Filed 7-22-99; 8:45 am]

BILLING CODE 4810-37-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 71-154a; FRL6400-1]

Clean Air Act Approval and Promulgation of California State Implementation Plan for the San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). The revisions are rules from the San Joaquin Valley Unified Air Pollution Control District (District). These rules were submitted by the State on behalf of the District to provide general permitting requirements and general provisions for the implementation of NSR and other SIP requirements for stationary sources in the District.

This approval action will incorporate these rules into the federally approved SIP. EPA is approving these rules to support District new source review (NSR) rules that are required by section 110(a) and part D of Clean Air Act as amended in 1990 (CAA or Act). These other rules, which are required for areas that have not attained the national

ambient air quality standards (NAAQS) for one or more pollutants, will be the subject of a subsequent rulemaking action. Thus, EPA is finalizing the approval of these general provisions and general permitting rules into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards, and plan requirements for nonattainment areas.

DATES: This rule is effective on September 21, 1999 without further notice, unless EPA receives adverse comments by August 23, 1999. If EPA receives such comment, it will publish a timely withdrawal in the **Federal Register** informing the public that EPA's approval of these rules will not take effect.

ADDRESSES: Comments must be submitted in writing to Ed Pike at the Region IX mailing address listed below. Copies of the rules and EPA's evaluation report are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are available for inspection at the following locations:

Permits Office (AIR-3), Air Division, Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, SW, Washington, DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95814

San Joaquin Valley Unified Air Pollution Control District, Central Region, 1990 E. Gettysburg Avenue, Fresno CA 93726

A courtesy copy of these rules may be available via the Internet at <http://arbis.arb.ca.gov/drdb/sju/cur.htm>. However, these versions of the District rules may be different than the versions submitted to EPA for approval. Readers are cautioned to verify that the adoption date of the rule listed is the same as the rule submitted to EPA for approval. The official submittal is only available at the four agency addresses listed above.

FOR FURTHER INFORMATION CONTACT: Ed Pike, (telephone 415/744-1211), Air Division (AIR-3), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901, or pike.ed@epa.gov.

SUPPLEMENTARY INFORMATION

I. Applicability

The rules being approved into the California SIP in this action are District Rules 1110, 1140, 1150, 2010, 2031,