

received no comments on the interim analysis. FDA also notes that this regulation simply articulates a procedure that will be used in the future to assess whether or not ozone-depleting substances in metered dose inhalers are essential.

FDA further certifies that the removal of essential-use designations for steroid nasal inhalation products that contain CFCs will not have a significant impact on a substantial number of small entities. The four affected manufacturers currently market alternative products at comparable prices. Therefore no net impact is expected from this regulation.

VIII. The Paperwork Reduction Act of 1995

This final rule does not require information collections subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Section 2.125(f) provides that a person may seek to add or remove an essential use listed under § 2.125(e) by filing a petition under part 10 (21 CFR part 10). Section 10.30(b) requires that a petitioner submit to the agency a statement of grounds, including the factual and legal grounds on which the petitioner relies. Section 2.125(f) describes the factual grounds necessary to document a petition to add or remove an essential use, as required by § 10.30(b). The burden hours required to provide the factual grounds for a petition have been calculated under § 10.30 and have been approved under OMB control number 0910-0183, which expires on February 28, 2003 (see 65 FR 12014, March 7, 2000).

IX. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The reference may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Drug Administration, Center for Drug Evaluation and Research, Pulmonary and Allergy Drugs Advisory Committee Transcript, Friedman & Associates, November 22, 1999.

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Devices, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Clean Air Act and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental

Protection Agency, 21 CFR part 2 is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 is revised to read as follows:

Authority: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

2. Section 2.125 is revised to read as follows:

§ 2.125 Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.

(a) As used in this section, *ozone-depleting substance* (ODS) means any class I substance as defined in 40 CFR part 82, appendix A to subpart A, or class II substance as defined in 40 CFR part 82, appendix B to subpart A.

(b) Except as provided in paragraph (c) of this section, any food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is not an essential use of the ODS under the Clean Air Act.

(c) A food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is an essential use of the ODS under the Clean Air Act if paragraph (e) of this section specifies the use of that product as essential. For drugs, including biologics and animal drugs, and for devices, an investigational application or an approved marketing application must be in effect, as applicable.

(d) [Reserved]

(e) The use of ODSs in the following products is essential:

(1) *Metered-dose corticosteroid human drugs for oral inhalation.* Oral pressurized metered-dose inhalers containing the following active moieties:

- (i) Beclomethasone.
- (ii) Dexamethasone.
- (iii) Flunisolide.
- (iv) Fluticasone.
- (v) Triamcinolone.

(2) *Metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation.* Oral pressurized metered-dose inhalers containing the following active moieties:

- (i) Albuterol.
- (ii) Bitolterol.
- (iii) Metaproterenol.
- (iv) Pirbuterol.
- (v) Epinephrine.

(3) [Reserved]

(4) *Other essential uses.* (i) Metered-dose salmeterol drug products

administered by oral inhalation for use in humans.

(ii) Metered-dose ergotamine tartrate drug products administered by oral inhalation for use in humans.

(iii) Anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application.

(iv) Metered-dose cromolyn sodium human drugs administered by oral inhalation.

(v) Metered-dose ipratropium bromide for oral inhalation.

(vi) Metered-dose atropine sulfate aerosol human drugs administered by oral inhalation.

(vii) Metered-dose nedocromil sodium human drugs administered by oral inhalation.

(viii) Metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use.

(ix) Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

(f) Any person may file a petition under part 10 of this chapter to request that FDA initiate rulemaking to amend paragraph (e) of this section to add an essential use. FDA may initiate notice-and-comment rulemaking to add an essential use on its own initiative or in response to a petition, if granted.

(1) If the petition is to add use of a noninvestigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the product without ODSs;

(ii) The product will provide an unavailable important public health benefit; and

(iii) Use of the product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the unavailable important public health benefit.

(2) If the petition is to add use of an investigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the investigational product without ODSs;

(ii) A high probability exists that the investigational product will provide an unavailable important public health benefit; and

(iii) Use of the investigational product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the high probability of an unavailable important public health benefit.

(g) Any person may file a petition under part 10 of this chapter to request

that FDA initiate rulemaking to amend paragraph (e) of this section to remove an essential use. FDA may initiate notice-and-comment rulemaking to remove an essential use on its own initiative or in response to a petition, if granted. If the petition is to remove an essential use from paragraph (e) of this section, the petitioner must submit compelling evidence of any one of the following criteria:

(1) The product using an ODS is no longer being marketed; or

(2) After January 1, 2005, FDA determines that the product using an ODS no longer meets the criteria in paragraph (f) of this section after consultation with a relevant advisory committee(s) and after an open public meeting; or

(3) For individual active moieties marketed as ODS products and represented by one new drug application (NDA):

(i) At least one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;

(ii) Supplies and production capacity for the non-ODS product(s) exist or will exist at levels sufficient to meet patient need;

(iii) Adequate U.S. postmarketing use data is available for the non-ODS product(s); and

(iv) Patients who medically required the ODS product are adequately served by the non-ODS product(s) containing that active moiety and other available products; or

(4) For individual active moieties marketed as ODS products and represented by two or more NDAs:

(i) At least two non-ODS products that contain the same active moiety are being marketed with the same route of delivery, for the same indication, and with approximately the same level of convenience of use as the ODS products; and

(ii) The requirements of paragraphs (g)(3)(ii), (g)(3)(iii), and (g)(3)(iv) of this section are met.

Dated: April 15, 2002.

Lester M. Crawford,

Deputy Commissioner.

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 523

[BOP-M06-F]

RIN 1120-AB05

District of Columbia Educational Good Time Credit

AGENCY: Bureau of Prisons, Justice.

ACTION: Interim final rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) describes procedures for awarding educational good time credit consistent with D.C. Code § 24-221.01 (DCEGT). This rule will apply to D.C. Code offenders in Bureau institutions or Bureau contract facilities under the National Capital Revitalization and Self-Government Improvement Act of 1997 (D.C. Revitalization Act), D.C. Code § 24-101(b), who committed their offenses before August 5, 2000. Through this rule, we will allow inmates sentenced under the D.C. Code to retain benefits permitted by the D.C. Code while fulfilling our statutory mandate to provide for their custody consistent with the sentence imposed.

DATES: This rule is effective on July 24, 2002. Comments are due by September 23, 2002.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307-2105.

SUPPLEMENTARY INFORMATION:

What Will This Rule Do?

Through this rule, the Bureau of Prisons (Bureau) will add a subpart D to its regulations in 28 CFR part 523, on Computation of Sentence. The new subpart D will establish procedures for awarding educational good time credit consistent with D.C. Code § 24-221.01. (We refer to educational good time credit consistent with the D.C. Code as "DCEGT.")

This rule will apply to D.C. Code offenders who committed their offense before August 5, 2000 and are in Bureau institutions or Bureau contract facilities under the D.C. Revitalization Act.

Why Are We Making This Rule?

We are making this rule to comply with the D.C. Revitalization Act, enacted August 5, 1997. This Act makes

the Bureau responsible for the "custody, care, subsistence, education, treatment and training" of "the felony population sentenced pursuant to the District of Columbia Code" (D.C. Code offenders). (D.C. Code § 24-101(b)) D.C. Code offenders in Bureau custody are subject to Federal laws and Bureau regulations as long as they are "consistent with the sentence imposed."

In August of 1997, when the D.C. Revitalization Act was enacted, the Bureau began absorbing approximately 8000 D.C. Code offenders. It was unclear at that time to what extent, if any, the Bureau would be bound by D.C. Code legislation which purported to direct Bureau functions.

As numerous D.C. Code provisions were analyzed for applicability to Bureau functions, it was generally concluded that the Bureau would have to follow D.C. Code sentence calculation provisions (e.g., good time, jail credit, etc.) to the extent non-compliance would result in an ex post facto violation of the offender's sentence. The Bureau based this approach on the provision in D.C. Revitalization Act requiring the Bureau to apply Federal laws to D.C. Code offenders "consistent with the sentence imposed."

The Bureau concluded that D.C. Code offenders who committed their offenses before August 5, 2000 are entitled to educational good time sentence credit. As a result, we developed these rules to give effect to the D.C. Code educational good time sentence credit (DCEGT) provisions in the Bureau's education and sentence calculation systems.

Section 24-221.01 of the D.C. Code provides for "educational good time credits of no less than 3 days a month and not more than 5 days a month" when a D.C. Code offender completes an educational program and obeys institution rules. This provision applies when a D.C. Code offender completes an educational program on or after April 11, 1987, when section 24-221.01 was enacted.

Section 24-403.01(d) of the D.C. Code, enacted April 23, 1998, however, requires that D.C. Code offenders who committed their offense on or after August 5, 2000, receive good time credit "only as provided in 18 U.S.C. 3624(b)." This statute in the Federal Criminal Code directs the Bureau how to award good time credit to U.S. Code offenders. Bureau regulations implementing this provision are in 28 CFR 523.20.

D.C. Code offenders who successfully complete an educational program on or after April 11, 1987, and who committed their offense before August 5, 2000, may receive educational good time credit consistent with D.C. Code