determining how to state the product's labeling.

The agency believes that relabeling costs of the type required by this direct final rule generally average about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). Assuming that there are about 25 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be $50,000 to $75,000. The agency believes that the actual cost could be lower for the reasons stated in the previous paragraph.

For the reasons stated previously and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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.

VII. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or three hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 347 is amended to read as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 1. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. Section 347.52 is amended by adding paragraphs (c)(4) and (e) and by revising paragraphs (d)(1)(i), (d)(1)(ii), and (d)(3) to read as follows:

§ 347.52 Labeling of astringent drug products.

* * * * *

(c) * * *

(4) *For products containing aluminum acetate identified in § 347.12(a) when labeled for use as a soak, compress, or wet dressing.* ''When using this product [bullet] in some skin conditions, soaking too long may overdry''.

(d) * * *

(1) * * *—(i) *For products used as a soak.* ''For use as a soak: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use''.

(ii) *For products used as a compress or wet dressing.* ''For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use''.

* * * * *

(3) *For products containing witch hazel identified in § 347.12(c).* ''Apply as often as needed''.

(e) *Products formulated and labeled as a styptic pencil and that meet the criteria established in § 201.66(d)(10) of this chapter.* The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(4) and (c)(5) may be presented as follows:

(i) The heading and indication required by § 201.66(c)(4) of this chapter may be limited to: ''Use [in bold type] stops bleeding of minor cuts from shaving''.

(ii) The ''external use only'' warning in § 347.52(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The second warning in § 347.52(c)(1) may state: ''avoid contact with eyes''. The warning in § 201.66(c)(5)(x) may be limited to the following: ''Keep out of reach of children.'' The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) may be omitted, provided the information after the heading ''Warning'' contains the warnings in this paragraph.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(3) and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14818 Filed 6–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–236S]

Schedules of Controlled Substances: Exempt Anabolic Steroid Products

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Suspension of interim rule.

SUMMARY: The DEA is suspending the order published January 15, 2003 designating two pharmaceutical preparations as exempt anabolic steroid products under the Controlled Substances Act (CSA). This suspension was brought about by the receipt of two

comments that raised significant issues regarding the order. This action is part of the ongoing implementation of the Anabolic Steroid Control Act (ASCA) of 1990.

EFFECTIVE DATE: June 13, 2003.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

The ASCA of 1990 (Title XIX of Pub. L. 101–647) placed anabolic steroids into Schedule III of the CSA (21 U.S.C. 812). Section 1903 of the ASCA provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the CSA (21 U.S.C. 801 *et seq.*) if the products have no significant potential for abuse. The authority to exempt these products was delegated from the Attorney General to the Administrator of the Drug Enforcement Administration (28 CFR 0.1009b), who, in turn, redelegated this authority to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (28 CFR appendix to subpart R, Section 7, paragraph (g)). The procedure for implementing this section of the ASCA is found in § 1308.33 of Title 21 of the Code of Federal Regulations.

In conformance with § 1308.33 of Title 21 of the Code of Federal Regulations, an application was received from Syntho Pharmaceuticals to exempt two of their anabolic steroid products, Syntest H.S. and Syntest D.S. This application was forwarded to the Secretary of Health and Human Services (HHS) for his evaluation. Upon the recommendation of HHS and other relevant information, the DEA published an interim rule and request for comments (68 FR 1964, January 15, 2003) in which the Deputy Assistant Administrator ordered the products to be added to the list of exempt anabolic steroids.

Suspension of Order To Add Anabolic Steroid Products to the List of Products Exempted From Application of the CSA

DEA received two comments from interested persons that raised significant issues regarding findings of fact or conclusions of law upon which this order was based. As set forth in 21 CFR 1308.33(d), the Deputy Assistant Administrator hereby immediately suspends the effectiveness of this order until she may reconsider the application in light of the comments and objections filed. Thereafter, the Deputy Assistant Administrator will reinstate, revoke, or amend her original order as she determines appropriate.

Dated: June 4, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–14901 Filed 6–12–03; 8:45 am]

BILLING CODE 4410–09–M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in July 2003. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

EFFECTIVE DATE: July 1, 2003.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in appendix B to part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in appendix B to part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in appendix C to part 4022).

Accordingly, this amendment (1) adds to appendix B to part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during July 2003, (2) adds to appendix B to part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during July 2003, and (3) adds to appendix C to part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during July 2003.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in appendix B to part 4044) will be 4.30 percent for the first 20 years following the valuation date and 5.25 percent thereafter. These interest assumptions represent a decrease (from those in effect for June 2003) of 0.40 percent for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in appendix B to part 4022) will be 3.00 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent a decrease (from those in effect for June 2003) of 0.50 percent for the period during which a benefit is in pay status and are otherwise unchanged.

For private-sector payments, the interest assumptions (set forth in appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during July 2003, the PBGC finds that good cause exists for making the assumptions set forth in this