Subject	Part
(5) Reentry of a Reentry Vehicle other than a Reusable Launch Vehicle (RLV)	435

Issued in Washington, DC, on June 10, 2003.

Donald P. Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 03–14995 Filed 6–12–03; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1260

NASA Grant and Cooperative Agreement Handbook—Unsolicited Proposals

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This final rule amends the NASA Grant and Cooperative Agreement Handbook to consolidate existing coverage regarding unsolicited proposals awarded as grants or cooperative agreements under a single new section.

EFFECTIVE DATE: June 13, 2003.

FOR FURTHER INFORMATION CONTACT: Paul Brundage, NASA Headquarters, Code HC, Washington, DC, (202) 358–0481, e-mail: *paul.brundage@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Coverage regarding unsolicited proposals awarded as grants or cooperative agreements is set out in different sections of NASA's Grant and Cooperative Agreement Handbook. This change consolidates and clarifies that coverage in a new § 1260.17.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* because the changes merely consolidates existing guidance.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not impose any new recordkeeping or information collection requirements, or collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et. seq.*

List of Subjects in 14 CFR Part 1260

Grant programs—science and technology.

Tom Luedtke,

Assistant Administrator for Procurement.

Accordingly, 14 CFR part 1260 is amended as follows:

■ 1. The authority citation for 14 CFR part 1260 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301, *et seq.*,) and OMB Circular A–110.

PART 1260—GRANTS AND COOPERATIVE AGREEMENT

■ 1. In section 1260.10, revise paragraph (a)(2) to read as follows:

§ 1260.10 Proposals.

(a) * * *

(2) An *unsolicited proposal.* (*See* § 1260.17.)

■ 2. In section 1260.11, revise paragraph (d) to read as follows:

§ 1260.11 Evaluation and selection.

(d) For unsolicited proposals, *see* § 1260.17.

■ 3. Add section 1260.17 to read as follows:

§ 1260.17 Evaluation and selection of unsolicited proposals.

(a) Unsolicited proposals are for new and innovative ideas. Federal Acquisition Regulation (FAR) 48 CFR Subpart 15.6 and NASA FAR Supplement (NFS) 48 CFR Subpart 1815.6 set out NASA's procedures for their submission and evaluation. Consult ''Guidance for the Preparation and Submission of Unsolicited Proposals'' (*see http://ec.msfc.nasa.gov/hq/library/unSol-Prop.html*) for additional information. NASA recommends contact with NASA technical personnel before submission of an unsolicited proposal to determine if preparation is warranted. These discussions should be limited to understanding NASA's need for research and do not jeopardize the unsolicited status of any subsequently submitted proposal.

(b) NASA will evaluate unsolicited proposals the same whether awarded as grants or contracts. However, the requirement to synopsize set out in FAR Part 5 does not apply to grants.

(c) All unsolicited proposals recommended for acceptance as grants shall be supported by a Justification for Acceptance of an Unsolicited Proposal (JAUP) prepared by the cognizant technical office. The JAUP shall be submitted for the approval of the grant officer after review and concurrence at a level above the technical officer. However, review and concurrence are not required for technical officers at a division chief or higher level. The grant officer's signature awarding the grant constitutes approval of the JAUP.

(d) If an unsolicited proposal will not be funded, NASA will notify in writing the organization or person that submitted it. The method of notification is at the discretion of the grant officer. Proposals will be returned only when requested.

(e) Because unsolicited proposals are awarded without competition, written justifications for equipment and travel shall be submitted by the technical office to the grant officer when more than half of the proposed budget is for equipment, travel, and their associated indirect costs. The grant officer's signature awarding the grant constitutes approval of the justification.

[FR Doc. 03–14935 Filed 6–12–03; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket No. 78N–021A]

RIN 0910–AA01

Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) skin protectant astringent drug products are generally recognized as safe and effective and not misbranded. This action revises some labeling for astringent drug products to be consistent with the final rule for OTC skin protectant drug products (68 FR 33362, June 4, 2003) and adds labeling for certain small packages (styptic pencils). This action is part of FDA's ongoing review of OTC drug products. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the

rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES:

Effective Date: This rule is effective October 27, 2003.

Compliance Dates: The compliance dates are either June 13, 2005, or the date of the first major labeling revision after the effective date of October 27, 2003, whichever occurs first.

Comment Dates: Submit written comments by August 27, 2003. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before September 26, 2003, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a document of significant adverse comments in the **Federal Register** and withdraw this direct final rule before September 26, 2003.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 21, 1993 (58 FR 54458), FDA published a final monograph for OTC skin protectant astringent drug products in part 347 (21 CFR part 347), subpart A (the 1993 skin protectant final monograph). In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA published a final rule for OTC skin protectant drug products (the 2003 skin protectant final monograph) and revised the format of part 347. Subpart A was redesignated as ''General Provisions,'' and the astringent active ingredients (§ 347.10) and labeling (§ 347.50) were redesignated as §§ 347.12 and 347.52, respectively.

Two ingredients (colloidal oatmeal and sodium bicarbonate) added to the skin protectant monograph are used as a soak, compress, or wet dressing similar to the astringent active ingredient aluminum acetate. In the 2003 skin protectant final monograph, the agency included a warning about soaking too long (§ 347.50(c)(7)) and included directions for colloidal oatmeal (§ 347.50(d)(2)) and sodium bicarbonate (§ 347.50(d)(3)) that are shorter than the directions for aluminum acetate (§ 347.52(d)(1)) and that are in the new OTC drug labeling format. In this direct final rule, the agency is adding this warning, shortening the directions for aluminum acetate drug products, and arranging these directions in the new OTC drug labeling format.

Section 201.66(d)(10) (21 CFR 201.66(d)(10)) of the OTC drug labeling rule (64 FR 13254 at 13286, March 17, 1999) establishes a modified labeling format for small packages that need more than 60 percent of their total surface area available to bear labeling to meet the requirements of § 201.66(c)(1) through (c)(9) and (d)(1) through (d)(9). The agency stated in that rule that it would consider additional approaches for accommodating certain products in their respective monographs, taking into consideration the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population (64 FR 13254 at 13270, March 17, 1999). The 2003 skin protectant final monograph included additional labeling exemptions for certain small packages (lip protectant products) that meet the size criteria established in § 201.66(d)(10). The agency determined that lip protectant/lip balm products are typically packaged in small amounts, applied to limited areas of the body, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings).

Consequently, the agency is now including additional labeling exemptions for certain small packages of skin protectant astringent drug products (styptic pencils) that meet the criteria established in § 201.66(d)(10), taking into consideration the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. For the safety profile of styptic pencils, the agency considered the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel). The Panel noted that ''In 75 years of marketing styptic pencils there have been [no] reported instances of human toxicity'' (47 FR 39412 at 39429, September 7, 1982). (The word ''no'' was inadvertently left out of the September 7, 1982, publication, and the agency corrected this error in its notice of proposed rulemaking for OTC skin protectant astringent drug products (54 FR 13490 at 13493, April 3, 1989).) The Panel also stated that aluminum sulfate (the active ingredient in styptic pencils) ''has little, if any, cell permeability and exerts its effect on the cell surface.'' The only side effect the Panel noted was that application of the styptic pencil on a cut may result in some stinging. Thus, these products have an extremely low risk in actual consumer use situations, and the monograph only requires two general warnings (§ 347.50(c)(1)) and no ingredient specific warnings.

The agency also considered the factors listed previously that were the basis for labeling modifications for OTC lip protectant/lip balm drug products. Like those products, styptic pencils are packaged in small amounts, have a high therapeutic index and a favorable public health benefit (stop bleeding), would be used infrequently and on very limited areas of the body to stop bleeding of minor cuts from shaving, require minimal warnings (there is no pregnancy warning because this is a topical product), and have no specified dosage limitation (the directions for use are to apply to the affected area). For these reasons, the agency is including specific labeling provisions for certain small packages of skin protectant astringent drug products (styptic pencils) in this direct final rule.

II. Description of the Labeling Revisions

The warning in § 347.50(c)(7), when the colloidal oatmeal or sodium bicarbonate product is labeled for use as a soak, compress, or wet dressing, states: ''When using this product [bullet] in some skin conditions, soaking too long may overdry.'' The agency is adding this warning in new § 347.52(c)(4) for products containing aluminum acetate when labeled for use as a soak, compress, or wet dressing. Our decision to revise the warning set forth in this direct final rule is based upon a finding that bathing can dry the skin out and exacerbate some conditions (as discussed in the 2003 skin protectant final monograph, 68 FR 33362 at 33367). Mandating a warning does not require a finding that any or all of the astringent drug products actually caused an adverse event, and FDA does not so find. Nor does FDA's mandate of a warning repudiate the OTC drug monograph under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that this revised warning is necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are

defined in the Federal Food, Drug, and Cosmetic Act.

FDA's decision to act in an instance such as this one need not meet the standard of proof required to prevail in a private tort action (*Glastetter* v. *Novartis Pharmaceuticals, Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)). To mandate a warning, or take similar regulatory action, FDA need not show, nor do we allege, actual causation.

The agency is revising the directions in § 347.52(d)(1)(i) for aluminum acetate used as a soak to read: ''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''. The agency is revising the directions in § 347.52(d)(1)(ii) for aluminum acetate used as a compress or wet dressing to read: ''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''. The agency is also shortening the directions in § 347.52(d)(3) for products containing witch hazel to read: ''apply as often as needed''.

The agency is adding new § 347.52(e) for products containing aluminum sulfate formulated as a styptic pencil. This section allows products that meet the criteria established in § 201.66(d)(10) to be marketed with reduced labeling.

III. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule revises several older labeling warnings and directions for OTC skin protectant astringent drug products for consistency with recently issued labeling for OTC skin protectant drug products and updates the labeling to the new OTC drug labeling format. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment by 75 days after the date of publication in the **Federal Register**, the agency will publish a document in the **Federal Register** confirming the effective date of the direct final rule. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the proposed rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this direct final rule and that part may be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on the direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

IV. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The rule that led to the development of this direct final rule was published on October 21, 1993, before the Unfunded Mandates Reform Act of 1995 was enacted. The agency explains in this direct final rule that the direct final rule will not result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

The agency concludes that this direct final rule is consistent with the principles set out in the Executive order and in these two statutes. The direct final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. FDA has determined that the direct final rule does not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this direct final rule is to make some minor labeling revisions in the previously issued astringents portion of the skin protectant drug products monograph to make the labeling consistent with the rest of the monograph and to add small package labeling provisions for aluminum sulfate marketed as a styptic pencil.

Current manufacturers of these products should incur only minor costs to relabel their products to meet the monograph. Some manufacturers will have to add a warning and revise the directions in their labeling. The agency is providing either 24 months from the date of publication of this direct final rule or the date of the first major labeling revision after the 135-day effective date of this direct final rule, whichever occurs first, for the manufacturers to use up existing labeling and print new labeling that incorporates the labeling in this direct final rule. Further, the labeling in the direct final rule is in the new OTC drug labeling format. Therefore, no additional professional skills are needed and manufacturers will not incur expenses

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