(Approved by the Office of Management and Budget under control number 0580–0016)

James E. Link,

Administrator, Grain Inspection, Packers and Stockyards Administration.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

RIN 3150–AH96

Facility Change Process Involving Items Relied on for Safety

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to clarify a requirement pertaining to items relied on for safety (IROFS). This rulemaking corrects an inconsistency in the regulations pertaining to IROFS.

DATES: The final rule is effective on December 11, 2006, unless significant adverse comments are received by October 27, 2006. As detailed in the Procedural Background section, a significant adverse comment is a comment where the commenter 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. If the NRC receives any significant adverse comments, the NRC will publish a document that withdraws the direct final rule and addresses the comments received in a final rule as a response to the companion proposed rule published elsewhere in this issue of the **Federal Register**.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150–AH96) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415–1966. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking website to Carol Gallagher (301) 415–5905; e-mail *cag@nrc.gov.* Comments can also be submitted via the Federal eRulemaking Portal *http://www.regulations.gov.*

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233, e-mail *ant@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Background

NRC's regulations at 10 CFR part 70 govern the domestic licensing of special nuclear material (SNM), including the licensing of uranium enrichment facilities. On September 18, 2000 (65 FR 56211), the NRC added subpart H requirements (§§ 70.60 to 70.76) to 10 CFR part 70. Subpart H applies to licensees possessing greater than a critical mass of SNM, such as those engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, and the scrap recovery of SNM. Section 70.61 sets forth performance requirements, and requires that the controls needed to meet the performance requirements be designated as IROFS. Section 70.62 requires the establishment of a safety program based on an integrated safety analysis (ISA). Under § 70.65, a summary of the ISA must be submitted to the NRC for approval, and the summary must contain the IROFS upon which the licensee relies in order to meet the performance requirements. In § 70.4, the definition of IROFS specifies that, in addition to the IROFS needed to meet the performance requirements in § 70.61 (i.e., the minimum set), a licensee may designate additional IROFS (i.e., beyond those in the minimum set necessary for compliance with the performance requirements).

The only revision to the subpart H requirements now being made is to 10 CFR 70.72(c)(2), as discussed further in this document.

Discussion

Section 70.72 contains requirements which control changes licensees (subject to subpart H) make to their facilities, and specifies criteria for determining if these changes require the NRC staff's review and approval before they are made. Section 70.72(c)(2) specifies that a licensee may remove an IROFS that is listed in the ISA summary, without prior NRC approval, if the licensee replaces the IROFS with an equivalent replacement of the safety function. Unlike other subpart H provisions (i.e., § 70.72(c)(3) and paragraphs (a)(4) and (a)(5) of Appendix A to Part 70), which distinguish between the minimum set of IROFS needed to meet the performance requirements and the larger set of IROFS a licensee may choose to identify, § 70.72(c)(2) does not make this distinction in stating as follows:

> (c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change * * *
>
> (2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary.

Questions have arisen about whether changes involving licensee-identified IROFS that are not needed to meet the

performance requirements in § 70.61 require an equivalent replacement of the safety function.

The staff is thus adding the phrase ''and is necessary for compliance with the performance requirements of § 70.61'' to the end of § 70.72(c)(2).

This revision clarifies that if an IROFS is not needed to meet the § 70.61 performance requirements, a licensee may remove or replace the IROFS without NRC staff's approval and without showing equivalent replacement of the safety function. This change does not affect IROFS needed to meet performance requirements. If a licensee intends to remove or replace an IROFS needed to meet performance requirements, then the licensee must obtain NRC staff's pre-approval before making the change, unless the licensee has demonstrated with on-site documentation that the replacement or removal of the IROFS could be done with equivalent replacement of the safety function of the IROFS.

Procedural Background

This rulemaking will become effective on December 11, 2006. However, if the NRC receives significant adverse comments by October 27, 2006, the NRC will publish a document that withdraws the direct final rule and addresses the comments received in a final rule as a response to the companion proposed rule published elsewhere in this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter 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 is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the staff to make a change (other than editorial) to the rule.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this portion of regulations is designated Category ''NRC'' and therefore is not a matter of Compatibility.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing'' directed that the Government's writing be in plain language. The NRC requests comments on this direct final rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading **ADDRESSES** above.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC is amending its regulations to clarify that the requirement in § 70.72(c)(2) applies only to the set of IROFS that are necessary to meet the § 70.61 performance requirements (i.e., the minimum set), and does not apply to IROFS beyond those in the minimum set. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this direct final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(2). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this direct final rule.

Paperwork Reduction Act Statement

This direct final rule decreases the burden on licensees to update the on-site documentation when a change covered by § 70.72 is made. The annual public burden reduction for this information collection is estimated to average 10 hours for each 8 licensees. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150–0009.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

A regulatory analysis has not been prepared for this direct final rule because this rule is considered a minor non-substantive amendment; it has insignificant economic impact on NRC licensees and the public.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule merely makes minor changes to the facility change process involving items relied on for safety. Additionally, the 10 CFR part 70 subpart H licensees affected by this rule are large organizations that do not fall within the definition of a small business as defined in the Regulatory Flexibility Act of the NRC's regulations (10 CFR 2.810).

Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 70

Hazardous materials transportation, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

■ For the reasons set out in the preamble and under the authority of the

Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 70.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

■ 1. The authority citation for part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835 as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

■ 2. In § 70.72, paragraph (c)(2) is revised to read as follows:

§ 70.72 Facility changes and change process.

* * * * *

(c) * * *

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary and is necessary for compliance with the performance requirements of § 70.61;

* * * * *

Dated at Rockville, Maryland, this 13th day of September 2006.

For the Nuclear Regulatory Commission.

Luis A. Reyes,

Executive Director for Operations.

[FR Doc. 06–8270 Filed 9–26–06; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Amprolium Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (ANADA) filed by IVX Animal Health, Inc. The ANADA provides for use of amprolium solution to make medicated drinking water or as a drench for the prevention or treatment of coccidiosis in calves.

DATES: This rule is effective September 27, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827-0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200–389 that provides for the use of Amprolium 9.6% Oral Solution to make medicated drinking water or as a drench for the prevention or treatment of coccidiosis in calves. IVX Animal Health's Amprolium 9.6% Oral Solution is approved as a generic copy of Merial Ltd.'s CORID (amprolium) 9.6% Solution approved under NADA 13–149. The ANADA is approved as of September 6, 2006, and the regulations are amended in 21 CFR 520.100 to reflect the approval and a current format. The 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 21 CFR 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 Division of Dockets Management (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.

FDA has determined under 21 CFR 25.33(a)(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 Subject 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. Revise § 520.100 to read as follows:

§ 520.100 Amprolium.

(a) *Specifications*—(1) Each milliliter of solution contains 96 milligrams (mg) amprolium (9.6 percent solution).

(2) Each gram of powder contains 200 mg amprolium (20 percent).

(3) Each ounce (28.4 grams) of crumbles contains 355 mg amprolium (1.25 percent).

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter.

(1) No. 050604 for use of products described in paragraph (a) of this section as in paragraph (e) of this section.

(2) No. 051311 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section.

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Chickens and turkeys*. It is used in drinking water as follows:

(i) *Amount*. Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks.

(ii)*Indications for use*. For the treatment of coccidiosis.

(iii) *Limitations*. Use as the sole source of amprolium.

(2) *Calves*. Administer crumbles top-dressed on or thoroughly mixed in the