

judicial action may be brought regarding the provisions of this rule the administrative appeal provisions of 7 CFR parts 11 and 780 must be exhausted.

#### Unfunded Mandates Reform Act of 1995

This rule contains no Federal mandates under the regulatory provisions of Title II of the UMRA for State, local, and tribal government or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

#### Paperwork Reduction Act

The Office of Management and Budget (OMB) previously approved the information collection requirements of the ECP under OMB control number 0560-0082. This rule will not change those information collection requirements. A separate notice requesting comments was published in the **Federal Register** on July 26, 2007 (72 FR 41051) for the information collection requirements for the collection of AGI information.

#### E-Government Act Compliance

FSA is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are: Emergency Conservation Program (ECP)—10.054.

#### List of Subjects in 7 CFR Part 701

Agriculture, Disaster assistance, Environmental protection, Forests and forest products, Grant programs—agriculture, Grant programs—natural resources, Reporting and recordkeeping, Rural areas, Soil conservation, Water resources, Wildlife.

■ Accordingly, amend 7 CFR part 701 as follows:

#### PART 701—EMERGENCY CONSERVATION PROGRAM AND CERTAIN RELATED PROGRAMS PREVIOUSLY ADMINISTERED UNDER THIS PART

■ 1. Revise the authority citation to read as follows:

**Authority:** Pub. L. 95-334, 92 Stat. 420, 16 U.S.C. 2201-2205; Pub. L. 109-148, Division B, sec. 101; and Pub. L. 110-28, secs. 9003-9004.

■ 2. Add new § 701.17 to read as follows:

#### § 701.17 Average Adjusted Gross Income Limitation

To be eligible for payments issued from the \$16 million provided under the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (Pub. L. 110-28, section 9003), each applicant must meet the provisions of the Adjusted Gross Income Limitations at 7 CFR part 1400 subpart G.

Signed at Washington, DC, on August 9, 2007.

**Glen L. Keppy,**

*Acting Administrator, Farm Service Agency.*

[FR Doc. E7-16175 Filed 8-15-07; 8:45 am]

**BILLING CODE 3410-05-P**

#### NUCLEAR REGULATORY COMMISSION

#### 10 CFR Part 72

RIN 3150-AI21

#### List of Approved Spent Fuel Storage Casks: TN-68 Revision 1

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Direct final rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is amending its spent fuel storage cask regulations by revising the Transnuclear, Inc. TN-68 dry storage cask system listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 1 to Certificate of Compliance (CoC) Number 1027. Amendment No. 1 will modify the CoC by revising several fuel parameters that include increasing fuel burnup to 60 gigawatts-day/metric ton of uranium, increasing total cask decay heat to 30 kilowatts, increasing maximum average fuel enrichment to 4.7 weight percent uranium-235, and decreasing minimum fuel assembly cooling time to 7 years. Amendment No. 1 will also add up to eight damaged fuel assemblies as authorized contents of the cask and reduce the cask spacing on the storage pad.

**DATES:** The final rule is effective October 30, 2007, unless significant adverse comments are received by September 17, 2007. 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 rule is withdrawn, timely notice will be published in the **Federal Register**.

**ADDRESSES:** You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AI21) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information, such as name, address, phone, e-mail address, etc., will not be removed from 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](mailto: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://rulemaking.llnl.gov>. Address questions about our rulemaking Web site to Carol Gallagher (301) 415-5905; e-mail [cag@nrc.gov](mailto: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 at the NRC's Public Document Room (PDR), O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can 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/NRC/ADAMS/index.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](mailto:pdr@nrc.gov). An electronic copy of the

CoC No. 1027, the revised Technical Specifications (TS), and the preliminary safety evaluation report (SER) for Amendment No. 1 can be found in a package under ADAMS Accession No. ML071170621.

CoC No. 1027, the revised TS, the preliminary SER for Amendment No. 1, and the environmental assessment are available for inspection at the NRC PDR, 11555 Rockville Pike, Rockville, MD. Single copies of these documents may be obtained from Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, e-mail [jmm2@nrc.gov](mailto:jmm2@nrc.gov).

**FOR FURTHER INFORMATION CONTACT:** Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, e-mail [jmm2@nrc.gov](mailto:jmm2@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended (NWSA), requires that “[t]he Secretary [of the Department of Energy (DOE)] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.” Section 133 of the NWSA states, in part, that “[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 218(a) for use at the site of any civilian nuclear power reactor.”

To implement this mandate, the NRC approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule in 10 CFR part 72, which added a new Subpart K within 10 CFR part 72, entitled “General License for Storage of Spent Fuel at Power Reactor Sites” (55 FR 29181; July 18, 1990). This rule also established a new Subpart L within 10 CFR part 72, entitled “Approval of Spent Fuel Storage Casks,” which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on

April 28, 2000 (65 FR 24855), that approved the TN-68 cask design and added it to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1027.

**Discussion**

On January 14, 2005, and as supplemented on July 15 and November 15, 2005; September 22 and December 8, 2006; and February 22, March 16, and March 23, 2007; the certificate holder, Transnuclear, Inc. (TN), submitted an application to the NRC that requested an amendment to CoC No. 1027. Specifically, TN requested revisions to several fuel parameters of the TN-68 cask design that included increasing fuel burnup to 60 gigawatts-day/metric ton of uranium (GWd/MTU), increasing total cask decay heat to 30 kilowatts (kW), increasing maximum average fuel enrichment to 4.7 weight percent uranium-235, and decreasing minimum fuel assembly cooling time to 7 years. The application also requested adding up to eight damaged fuel assemblies as authorized contents of the cask and reducing the cask spacing on the storage pad. No other changes to the TN-68 dry storage cask system were requested in this application. As documented in the SER, the NRC staff performed a detailed safety evaluation of the proposed CoC amendment request and found that an acceptable safety margin is maintained. In addition, the NRC staff has determined that there continues to be reasonable assurance that public health and safety and the environment will be adequately protected.

This direct final rule revises the TN-68 dry storage cask system listing in 10 CFR 72.214 by adding Amendment No. 1 to CoC No. 1027. The amendment consists of the changes described above as set forth in the revised CoC and TS. The particular TS which are changed are identified in the SER.

The amended TN-68 cask design, when used under the conditions specified in the CoC, the TS, and NRC regulations, will meet the requirements of Part 72; thus, adequate protection of public health and safety will continue to be ensured. Once this direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into TN-68 casks that meet the criteria of Amendment No. 1 to CoC No. 1027, in accordance with 10 CFR 72.212.

**Discussion of Amendments by Section**

*Section 72.214 List of Approved Spent Fuel Storage Casks*

Certificate No. 1027 is revised by adding the initial certificate effective

date of May 30, 2000, and the effective date of Amendment No. 1.

**Procedural Background**

This rule is limited to the changes contained in Amendment No. 1 to CoC No. 1027 and does not include other aspects of the TN-68 dry storage cask system. The NRC is using the “direct final rule procedure” to issue this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on October 30, 2007. However, if the NRC receives significant adverse comments on this direct final rule by September 17, 2007, then the NRC will publish a document that withdraws this action and will subsequently address 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 NRC staff to make a change (other than editorial) to the rule, CoC, or TS.

**Voluntary Consensus Standards**

The National Technology Transfer and Advancement 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 will revise the TN-68 cask design listed in § 72.214 (List of NRC-approved spent fuel storage cask designs). This action does not constitute the establishment of a standard that contains generally applicable requirements.

#### 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 rule is classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

#### Plain Language

The Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible 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.

#### Finding of No Significant Environmental Impact: Availability

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in Subpart A of 10 CFR Part 51, the NRC has determined that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has prepared an environmental assessment and, on the basis of this environmental assessment, has made a finding of no significant impact. This rule will amend the CoC for the TN-68 cask design within the

list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. The amendment will revise several fuel parameters that include increasing fuel burnup to 60 GWd/MTU, increasing total cask decay heat to 30 kW, increasing maximum average fuel enrichment to 4.7 weight percent uranium-235, and decreasing minimum fuel assembly cooling time to 7 years. The amendment will also add up to eight damaged fuel assemblies as authorized contents of the cask and reduce the cask spacing on the storage pad. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the environmental assessment and finding of no significant impact are available from Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, e-mail [jmm2@nrc.gov](mailto:jmm2@nrc.gov).

#### Paperwork Reduction Act Statement

This direct final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150-0132, 10 CFR Part 72.

#### 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

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR Part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. A list of NRC-approved cask designs is contained in 10 CFR 72.214. On April 28, 2000 (65 FR 24855), the NRC issued an amendment to Part 72 that approved the TN-68 cask design by adding it to the

list of NRC-approved cask designs in 10 CFR 72.214. On January 14, 2005, and as supplemented on July 15 and November 15, 2005; September 22 and December 8, 2006; and February 22, March 16, and March 23, 2007; the certificate holder, TN, submitted an application to the NRC to amend CoC No. 1027 to revise several fuel parameters that included increasing fuel burnup to 60 GWd/MTU, increasing total cask decay heat to 30 kW, increasing maximum average fuel enrichment to 4.7 weight percent uranium-235, and decreasing minimum fuel assembly cooling time to 7 years. The application also requested adding up to eight damaged fuel assemblies as authorized contents of the cask and reducing the cask spacing on the storage pad.

The alternative to this action is to withhold approval of Amendment No. 1 and to require any part 72 general licensee, seeking to load spent fuel into TN-68 casks under Amendment No. 1, to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested Part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of the direct final rule is consistent with previous NRC actions. Further, as documented in the SER and the environmental assessment, the direct final rule will have no adverse effect on public health and safety. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of the direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and thus, this action is recommended.

#### Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and TN. These entities do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

## Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required.

## Congressional Review Act

Under 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, Office of Management and Budget.

## List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

■ 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; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72.

## PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

**Authority:** Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–10 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

■ 2. In § 72.214, Certificate of Compliance 1027 is revised to read as follows:

### § 72.214 List of approved spent fuel storage casks.

\* \* \* \* \*

Certificate Number: 1027.  
Initial Certificate Effective Date: May 30, 2000.  
Amendment Number 1 Effective Date: October 30, 2007.  
SAR Submitted by: Transnuclear, Inc.  
SAR Title: Final Safety Analysis Report for the TN–68 Dry Storage Cask.  
Docket Number: 72–1027.  
Certificate Expiration Date: May 28, 2020.  
Model Number: TN–68.

\* \* \* \* \*

Dated at Rockville, Maryland, this 31st day of July, 2007.

For the Nuclear Regulatory Commission.

**Martin J. Virgilio,**

*Acting Executive Director for Operations.*

[FR Doc. E7–16134 Filed 8–15–07; 8:45 am]

BILLING CODE 7590–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 606, 607, 610, and 640

[Docket No. 2007N–0264]

### Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components and Source Plasma to be more consistent with current practices in the blood industry and to remove

unnecessary or outdated requirements. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection.

Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under our usual procedures for notice and comment in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

**DATES:** This direct final rule is effective February 19, 2008. Submit written or electronic comments by October 30, 2007. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date of this direct final rule confirming that the direct final rule will go into effect on February 19, 2008. If we receive any significant adverse comments during the comment period, we intend to withdraw this direct final rule before its effective date by a notice published in the **Federal Register**.

**ADDRESSES:** You may submit comments, identified by Docket No. 2007N–0264, by any of the following methods:  
*Electronic Submissions*  
Submit electronic comments in the following ways:

• Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

• Agency Web site: <http://www.fda.gov/dockets/comments>. Follow the instructions for submitting comments on the agency Web site.

*Written Submissions*  
Submit written submissions in the following ways:

• FAX: 301–827–6870.  
• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and