rule that was published in the **Federal Register** on January 10, 2000, (65 FR 1309), Airspace Docket No. 99–ASO–27.

EFFECTIVE DATE: January 26, 2000.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document DOCID: fr10ja00–6, Airspace Docket No. 99–ASO–27, published on January 10, 2000, (65 FR 1309), amended Class D surface area airspace at Jacksonville Whitehouse NOLF, FL. An error was discovered in the amendatory language identifying the airspace description. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the publication for describing Jacksonville Whitehouse NOLF, FL, Class D surface area airspace at Jacksonville Whitehouse NOLF, FL, as published in the **Federal Register** on January 10, 2000, (65 FR 1309), (**Federal Register** Document DOCID: fr10ja00–6; page 1309), is corrected as follows:

Section 71.1 [Corrected]

* * * * *

ASO FL D Jacksonville Whitehouse NOLF, FL [Corrected]

By removing ''be effective during the specific dates and times established in advance by a Notice to''

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Issued in College Park, Georgia, on January 10, 2000.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–1815 Filed 1–25–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ANE–92]

Establishment of Class E Airspace; Burlington, VT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; correction; confirmation of effective date.

SUMMARY: This notice confirms the effective date of a direct final rule that establishes Class E airspace area at Burlington, VT (KBTV) to provide for adequate controlled airspace for aircraft executing instrument approaches to the Burlington International Airport at times when the Burlington Air Traffic Control Tower is closed. This action also corrects a typographical error in the docket number and changes the longitude and latitude of the Burlington International Airport to reflect North American Datum (NAD) 1983.

EFFECTIVE DATE: The direct final rule published at 64 FR 68008 is effective 0901 UTC, February 24, 2000.

FOR FURTHER INFORMATION CONTACT: David T. Bayley, Air Traffic Division, Airspace Branch, ANE–520.3, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7586; fax (781) 238–7596.

SUPPLEMENTARY INFORMATION:

The FAA published this direct final rule with a request for comments in the **Federal Register** on December 6, 1999 (64 FR 68008). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on February 24, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

This direct final rule also corrects the docket number for this action to 99–ANE–92. The docket number used for the publication of the direct final rule was previously used for another airspace action. That other action, however, was issued from FAA Headquarters, while this action was issued from the New England Region. Therefore, the FAA has determined that the error in the docket number caused no confusion to interested persons wishing to comment on this proposal and corrects the docket number in this action.

Lastly, the longitude and latitude coordinates published in the direct final rule must be updated to reflect North American Datum (NAD) 1983. The FAA has determined that neither of these corrections expands the scope of the direct final rule.

Correction to the Direct Final Rule

Accordingly, pursuant to the authority delegated to me, the establishment of Class E airspace at Burlington, VT as published in the **Federal Register** on December 6, 1999 (64 FR 68008), **Federal Register** document 99–31518: page 68009, column 2; and the description in FAA Order 7400.9G, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.7; are corrected to read as follows:

Subpart E—Class E Airspace

* * * * **

Paragraph 6002—Class E Airspace Areas Designated as Extending Upward From the Surface of the Earth

* * * * **

ANE VT E2 Burlington, VT [New]

Burlington International Airport, VT (Lat. 44°28′23″ N, long. 73°09′01″ W.)

Within a 5-mile radius of Burlington International Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airman. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Burlington, MA, on January 13, 2000.

William C. Yuknewicz,

Acting Manager, Air Traffic Division, New England Region.

[FR Doc. 00–1814 Filed 1–25–00 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0056]

RIN 0910–AA74

Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to add certain labeling requirements for aluminum content in large volume parenterals (LVP's), small

volume parenterals (SVP's), and pharmacy bulk packages (PBP's) used in total parenteral nutrition (TPN). FDA is also specifying an upper limit of aluminum permitted in LVP's and requiring applicants to submit to FDA validated assay methods for determining aluminum content in parenteral drug products. The agency is adding these requirements because of evidence linking the use of parenteral drug products containing aluminum to morbidity and mortality among patients on TPN therapy, especially among premature neonates and patients with impaired kidney function.

DATES: This rule is effective January 26, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a notice of intent in the **Federal Register** on May 21, 1990 (55 FR 20799) announcing FDA's concerns about toxic aluminum levels in TPN and requesting comments. As a result of the comments received, on January 5, 1998, FDA published a proposed rule in the **Federal Register** (63 FR 176) in which it proposed to: (1) Establish a maximum permissible level of aluminum in LVP's used in TPN therapy; (2) require that the maximum level of aluminum permitted in LVP's used in TPN therapy be stated on the package insert of all LVP's used in TPN therapy; (3) require that the maximum level of aluminum at expiry be stated on the immediate container label of SVP's and PBP's used in the preparation of TPN solutions; (4) require that the package insert of all LVP's and SVP's, including PBP's, contain a warning statement about aluminum toxicity in patients with impaired kidneys and neonates receiving TPN therapy; and (5) require that applicants and manufacturers develop validated assay methods for determining the aluminum content in parenteral drug products used in TPN therapy and submit the validated assay methods to FDA for approval.

FDA has become increasingly concerned about the aluminum content in parenteral drug products, which could result in a toxic accumulation of aluminum in the tissues of individuals receiving TPN therapy. FDA included specific references in the proposed rule that supported the following information about aluminum toxicity (63 FR 176). Research indicates that neonates and patient populations with impaired kidney function may be at high risk of exposure to unsafe amounts of aluminum. Many drug products used routinely for TPN may contain levels of aluminum sufficiently high to cause clinical manifestations. Generally, when medication and nutrition are administered orally, the gastrointestinal tract acts as an efficient barrier to the absorption of aluminum, and relatively little ingested aluminum actually reaches body tissues. However, parenterally administered drug products containing aluminum bypass the protective mechanism of the gastrointestinal tract and aluminum circulates, and it is deposited in human tissues.

Aluminum toxicity is difficult to identify in neonates because few reliable techniques are available to evaluate bone metabolism in premature neonates. Techniques used to evaluate the effects of aluminum on bone in adults cannot be used in premature neonates. Although aluminum toxicity is not commonly detected clinically, it can be serious in selected patient populations, such as neonates, and may be more common than is recognized.

Classic manifestations of aluminum intoxication in patients with impaired kidney function include fracturing osteomalacia, encephalopathy, and microcytic hypochromic anemia. Aluminum may prevent calcium absorption in premature neonates receiving TPN therapy. In addition, aluminum loading may be a factor in the bone disease of very ill neonates with reduced kidney function who have received long-term parenteral therapy with aluminum-contaminated fluids.

FDA received 21 comments on the proposed rule and addresses each of those comments in section III of this document. FDA is adopting this final rule as described below. The agency has also made minor edits to the final rule in response to the President's June 1, 1998, memorandum on plain language in Government writing.

II. Highlights of the Final Rule

FDA is implementing this final rule because of evidence linking the use of parenteral drug products containing aluminum to morbidity and mortality among patients on TPN therapy, especially premature neonates and patients with impaired kidney function.

The new regulations added to part 201 ((21 CFR 201) at § 201.323(a)) limit the aluminum content for all LVP's used in TPN therapy to 25 micrograms per liter (µg/L). This requirement applies to all LVP's used in TPN therapy, including, but not limited to, parenteral amino acid solutions, highly concentrated dextrose solutions, parenteral lipid emulsions, saline and electrolyte solutions, and sterile water for injection.

New § 201.323(b) requires the package insert for all LVP's used in TPN therapy to state that the drug product contains no more than 25 µg/L of aluminum. This statement must be included in the ''Precautions'' section of the labeling.

New § 201.323(c) requires the product's maximum level of aluminum at expiry to be stated on the immediate container label of SVP's and PBP's used in the preparation of TPN solutions. The statement on the immediate container label must read as follows: ''Contains no more than —— µg/L of aluminum.'' For those SVP's and PBP's that are lyophilized powders used in the preparation of TPN solutions, the maximum level of aluminum at expiry must be printed on the immediate container label as follows: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than —— µg/L.'' The maximum level of aluminum must be stated as the highest of: (1) The highest level for the batches produced during the last 3 years; (2) the highest level for the latest five batches, or (3) the maximum historical level, but only until completion of production of the first five batches after January 26, 2001. The labeling requirement applies to all SVP's and PBP's used in the preparation of TPN solutions, including, but not limited to: Parenteral electrolyte solutions, such as calcium chloride, calcium gluceptate, calcium gluconate, magnesium sulfate, potassium acetate, potassium chloride, potassium phosphate, sodium acetate, sodium lactate, and sodium phosphate; multiple electrolyte additive solutions; parenteral multivitamin solutions; single-entity parenteral vitamin solutions, such as vitamin K injection, folic acid, cyanocobalamin, and thiamine; and trace mineral solutions, such as chromium, copper, iron, manganese, selenium, and zinc.

New § 201.323(d) requires the package insert for all LVP's, SVP's, and PBP's used in TPN to contain a warning statement. The warning statement must be included in the ''Warnings'' section of the labeling. The warning must contain the following language:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

FDA removed the phrase ''intended for patients with impaired kidney function and for neonates receiving TPN therapy'' from the first sentence of § 201.323(d) because the phrase duplicated information contained in the actual warning and because the phrase made the first sentence of § 201.323(d) unclear.

New § 201.323(e) requires applicants and manufacturers to use validated assay methods to determine the aluminum content in parenteral drug products used in TPN therapy. The assay methods must comply with current good manufacturing practice regulations under part 211 (21 CFR part 211) (see § 211.194(a)). Holders of approved applications for LVP's, SVP's, and PBP's used in TPN therapy are required to submit a supplement to FDA under § 314.70(c) (21 CFR 314.70(c); see also 21 U.S.C. 356a(b)) describing the assay method used for determining the aluminum content. Applicants must submit the validation method used and the release data for several batches. In addition, manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections (see 21 CFR 211.160 and 211.180(c)).

New § 201.323 applies to all human drug LVP's, SVP's, and PBP's used in TPN. Licensed biological products are not covered by this rule.

III. Comments on the Proposed Rule

FDA received 21 comments on the proposed rule from professional associations, prescription drug manufacturers, Congress, individuals on TPN, and a hospital. Most comments supported the proposed limit for aluminum content in LVP's and the labeling requirement for SVP's and PBP's. Four comments suggested changes to the proposed warning statement. A summary of the comments received and the agency's responses follow.

A. Levels of Aluminum Content in LVP's

The agency stated in the proposed rule that it was considering setting an upper limit of 25 µg/L for LVP's used in TPN therapy. This requirement would apply to all LVP's used in TPN therapy, including, but not limited to, parenteral amino acid solutions, highly concentrated dextrose solutions, parenteral lipid emulsions, saline and electrolyte solutions, and sterile water for injection. The agency also proposed that the package insert for all LVP's used in TPN therapy state that the drug product contains no more than 25 µg/L.

1. Fifteen comments strongly supported a limit on aluminum of 25 µg/L. Two of the comments specifically supported the accompanying proposal that the package insert state that the drug product contains no more than 25 µg/L of aluminum.

FDA agrees that 25 µg/L of aluminum is a reasonable limit. As stated in the proposed rule, the 25 µg/L limit is feasible and necessary for the safe and effective use of LVP's used in TPN therapy.

Two comments, one from an LVP manufacturer and the other from a trade association, stated that 25 µg/L is not a reasonable limit for the varying reasons outlined in comments 2 through 8, in section III. A of this document.

2. These comments stated that data from production batches show potential rejections of finished batches at release if a limit of 25 µg/L is adopted. One of these comments specified that more than 10 percent of assay results exceed the proposed limit. It also stated that their current batch analysis showed a 95 percent confidence that at least 99 percent of the batch contained less than 50.37 µg/L of aluminum at release.

FDA understands that not all current batches of LVP's will meet a 25 µg/L level of aluminum. FDA will implement this rule 1 year after the date of publication to allow companies an opportunity to meet the specifications in this rule. FDA is not adopting a higher level because FDA believes a 25 µg/L level of aluminum is necessary to protect the public health.

3. The same two comments said that glass leaching over time increases aluminum levels so that initial levels cannot be established low enough to ensure batch acceptability by the end of the expiry period.

The intention of this rule is to reduce aluminum to an acceptable level in TPN products. A manufacturer can reduce toxicity by any of several routes, including using containers made of different materials.

4. One of these comments requested that FDA set the maximum level of aluminum using the procedure specified in the draft guidance entitled ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances'' (draft Q6A guidance) (62 FR 62890). This draft guidance states that a limit on impurities can be determined by (1) Determining the level at which the impurity is present in relevant batches and then (2) determining the mean plus upper confidence limit for the impurity where the upper confidence limit is three times the standard deviation of batch analysis data.

FDA is not using the procedures specified in the draft Q6A guidance because it is not appropriate to use current product aluminum levels to determine upper limits when the goal is to reduce aluminum levels to at or below the limit defined as safe. Further, the guidances entitled ''Q3A: Impurities in New Drug Substances,'' (January 1996) and ''Q3B Impurities in New Drug Products,'' (November 1997) address the issue of quantification of impurities. These guidances state that limits should be set no higher than the level that can be justified by safety data. The guidances also state that, for impurities known to be unusually potent or to produce toxic or unexpected pharmacological effects, the quantitation and detection limit of the analytical methods should be commensurate with the level at which the impurities must be controlled. FDA's primary concern in enacting this rule is ensuring the safety of the patient population and limiting exposure to the impurity. FDA has determined that the 25 µg/L limit is necessary for the safe and effective use of LVP's in TPN therapy.

5. These comments also stated that current assay methods cannot reliably distinguish between 25 µg/L and 30 µg/L. The comment did not provide supporting data or evaluation of the specific methods claimed to lack the required accuracy.

FDA understands that methods are currently available that are capable of detecting aluminum concentrations at 25 µg/L levels. In particular, FDA is aware that graphite furnace atomic absorption spectrometometry can be a sufficiently accurate validation method. However, FDA will accept any validated analytical method to assay aluminum content in TPN.

6. One of these comments suggested that FDA should require labeling of LVP's with an average and a range of aluminum values at expiry, obtained from five production scale batches, instead of requiring a limit of 25 µg/L

of aluminum in LVP's. The labeling would state ''Approximate average aluminum value— µg/L. Approximate aluminum range —— µg/L to — µg/L.'' The same comment requested that FDA apply the same labeling standards to LVP's, SVP's, and PBP's, under the rationale that some LVP's are identical in composition to PBP's.

FDA notes that if a manufacturer makes a PBP specifically for LVP use, the PBP should not contain more than 25 µg/L of aluminum so that the LVP manufactured from the PBP does not contain more than 25 µg/L of aluminum. FDA is implementing the 25 µg/L limit for LVP's rather than permitting an average or a range of aluminum levels to be stated for LVP's because the agency believes that it is more appropriate to set a maximum level due to the large volume of use of these products. FDA has determined that the 25 µg/L limit is necessary for the safe and effective use of LVP's used in TPN therapy. FDA's basis for not requiring SVP's and PBP's to be labeled with an average and a range of aluminum levels is discussed in response to comment 11 in section III. B of this document.

7. This same comment stated that establishing a 25 µg/L limit on LVP's would not have the desired effect of reducing aluminum levels in TPN because the majority of aluminum contamination is due to SVP's, not LVP's. A different comment requested that FDA narrow coverage of the rule to only those products that contribute significant amounts of aluminum to TPN: Calcium gluconate, calcium gluceptate, potassium phosphates, and sodium phosphates. The comment stated that calcium gluconate alone can contribute 88 percent of the total aluminum present in a TPN formulation.

FDA recognizes that numerous factors contribute to aluminum contamination in TPN therapy. Therefore, FDA is addressing the problem in several different ways in an effort to reduce aluminum contamination, rather than reducing aluminum from one source.

8. Another comment noted that the United States Pharmacopeia (USP) has limited aluminum levels in monographs for substances used in hemodialysis, including: Calcium acetate, calcium chloride, magnesium chloride, potassium chloride, sodium acetate, sodium bicarbonate, and sodium chloride. The comment stated that additional steps could be taken to limit aluminum levels in monographs of substances used in the manufacture of TPN solutions. Although FDA believes USP's limits add a valuable contribution to limiting aluminum contamination, FDA believes the additional measures set forth in this final rule are needed to prevent an unsafe level of aluminum in TPN.

B. Aluminum Levels in SVP's and PBP's

In the proposed rule, FDA proposed requiring that the maximum level of aluminum at expiry be stated on the immediate container label of SVP's and PBP's used in the preparation of TPN solutions. FDA proposed that the statement on the immediate container label read as follows: ''Contains no more than —— µg/L of aluminum.'' For those SVP's and PBP's that are lyophilized powders used in the preparation of TPN solutions, FDA proposed that the maximum level of aluminum at expiry be printed on the immediate container label as follows: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than—— µg/L.'' FDA proposed that the maximum level of aluminum must be expressed as the highest of: (1) The highest level for the batches produced during the last 3 years; (2) the highest level for the latest five batches; or (3) the maximum historical level, but only until completion of production of the first five batches after the rule takes effect.

9. Two comments supported FDA's proposal. One comment requested that FDA further specify limitations on aluminum content for SVP's.

FDA plans to implement the labeling requirements for SVP's and PBP's as proposed. FDA does not consider it appropriate to consider SVP's as a single category because SVP's are used for many indications other than TPN and in target populations where aluminum toxicity is not an issue.

10. One comment asked that FDA set a minimum level below which the amount of aluminum would not need to be declared.

FDA believes it is important for health care practitioners to know as much as possible about the aluminum levels being consumed by their patients. FDA believes the knowledge that a product has a low level of aluminum is just as important as the knowledge that a product contains high levels of aluminum. This labeling requirement permits health care professionals administering the drug to be able to calculate the total aluminum exposure the patient receives from multiple sources, and to be able to make appropriate substitutions to prepare ''low aluminum'' parenteral solutions for use in patients who are in high risk groups. Therefore, FDA believes all LVP's, SVP's, and PBP's used in TPN should be labeled with their aluminum levels.

11. One comment stated that information about the average amount of aluminum and its range at expiration for LVP's and SVP's is more useful than the maximum historical value at expiration, since otherwise a physician may overestimate the amount of aluminum being delivered to the patient. Another comment proposed that FDA require labeling of SVP's and PBP's with an average and a range of aluminum values at expiry, obtained from five production scale batches, such that the labeling would state ''Approximate average aluminum value —— µg/L. Approximate aluminum range —— µg/L to—— µg/L.''

The agency believes that information about the maximum concentration of aluminum potentially present at expiry is more useful to the practitioner. FDA's intention is to limit exposure to aluminum, and the use of average values or range at expiration would not achieve this goal as effectively.

C. Applicability to Biologics

In the proposed rule, FDA stated that licensed biological products were not covered by the proposal.

12. Twelve comments stated that biologics, specifically albumin, plasminate, and any other colloidal volume expanders, should be regulated. The Center for Biologics Evaluation and Research at the FDA is currently considering whether to regulate the levels of aluminum in licensed biological products. However, such regulation is outside the scope of this final rule.

D. Statement Regarding Maximum Intake of Aluminum

FDA proposed requiring a statement regarding the maximum daily aluminum intake recommended for patients. FDA sought comment on whether adding the language ''Patients should receive no more than 4 to 5 µg/kg/day of aluminum'' to the warning statement was appropriate and on whether a 4 to 5 µg/kilogram (kg)/day level is reasonable and adequate to protect the public health.

13. Two comments stated that FDA should include definitions of safe, unsafe, and toxic levels of aluminum. Three comments said that FDA should provide health professionals with a best estimate as to what constitutes a toxic aluminum load.

One comment stated that proposing to limit aluminum to 4 to 5 µg/kg/day would either make TPN formulations unavailable to neonates or expose doctors to liability, because it is a

difficult level to meet. Another comment said that 4 to 5 µg/kg/day is too low and may not allow patients to receive adequate amounts of calcium and phosphates. One comment noted that parenteral limits are much lower than oral limits, and expressed the belief that the proposed language did not offer guidance with respect to combined oral and parenteral daily limits. Another comment noted that the proposal does not provide a therapeutic alternative to too high aluminum levels, and asked that FDA include in the statement a definition of the populations truly at risk.

One comment stated that it would be difficult for health care professionals to calculate total aluminum intake, particularly for neonates receiving multiple intravenous infusions. Another comment stated that the factors that affect plasma aluminum clearance [1] can influence sensitivity to aluminum load [2] at any concentration of aluminum infused, and therefore aluminum concentration in TPN cannot be correlated directly to aluminum plasma levels.

Two comments recommended alternative statements. One suggested using the following language: ''Daily parenteral intake of greater than 4 to 5 µg/kg/day of aluminum has been associated with central nervous system and bone toxicity.'' Another suggested using the following warning: ''No aluminum toxicity to the brain or bone of premature neonates has been documented with intakes below 5 µg/kg/day; however, tissue loading may still occur at that rate of administration to preterm infants.''

One comment requested that FDA require such a warning statement only for those SVP's for which aluminum is a significant problem.

Based on these comments, FDA revised the warning to include a statement on current findings rather than a statement about maximum safe levels. FDA included specific references in the proposed rule (63 FR 176).

E. Acceptable Assay Methods for Determining Aluminum Levels

FDA proposed permitting applicants and manufacturers to have the discretion and flexibility to develop their own validated assay methods as long as the methods are in compliance with current good manufacturing practices requirements. Holders of approved applications for LVP's, SVP's and PBP's used in TPN therapy would be required to submit a supplement under part 314 (21 CFR part 314) in § 314.70(c) that described the method used for determining aluminum content. Holders of pending applications would be required to submit an amendment under § 314.60 or § 314.96. For SVP's not subject to approved applications, manufacturers would be required to maintain records for examination by FDA during inspections.

14. One comment stated that the USP provides an established system and procedure for the development of uniform analytical methods. The comment asked that FDA request that U.S.P. develop assay methods for determining aluminum content in parenterals rather than requiring individual companies to do so.

FDA believes that more than one analytical method may be suitable or necessary to assay aluminum content in different TPN products. Once FDA has reviewed several methods, it may evaluate whether it is appropriate to develop uniform analytical procedures. Individual companies may provide their validated analytical methods to USP for publication. Through this process, USP may establish a uniform analytical method for determining aluminum content in parenterals. FDA will accept any method that is validated and in compliance with current good manufacturing practice requirements.

15. One comment supported FDA's proposal. The comment also stated that analytical methods should be those in general use, such as flameless atomic absorption spectroscopy with a graphite furnace, and the method should be sufficiently sensitive to detect aluminum at the µg/L and not the milligram (mg) per liter level.

Again, FDA will accept any method that is validated and in compliance with current good manufacturing practice requirements. Any analytical method must be sensitive enough to detect aluminum at the µg/L and not the mg/L level, because the aluminum limits for LVP's and the required labeling statements for LVP's, SVP's, and PBP's are measured in µg/L.

F. Date of Implementation of the Final Rule

FDA proposed that any final rule that issued based on its proposed rule would become effective 1 year after the final rule's date of publication in the **Federal Register**. After that date, new drug applications (NDA's) submitted under § 314.50 and abbreviated new drug applications (ANDA's) submitted under 21 CFR 314.94 would have to comply with the new requirements under § 201.323.

16. One comment proposed an implementation date of 4 years after publication of the final rule in the **Federal Register** to account for the time necessary to collect and analyze data. Another comment suggested an implementation date of 31/2 years after publication of the final rule, or whenever data from five batches of product became available and the supplement was approved. This comment stated that the additional time is necessary to collect aluminum levels at expiry by an appropriate and validated method, since companies do not presently have such data.

Under the final rule, a manufacturer may use: (1) The highest level for the batches produced during the last 3 years; (2) the highest level for the latest five batches, or (3) the maximum historical level, but only until completion of production of the first five batches after this rule takes effect. This means that if expiry data under (1) and (2) of comment 16 in section III. F of this document are not available within 1 year, data available for the product during that year can be used under (3) of comment 16. As a manufacturer accrues additional data, it can then also use methods (1) and/or (2) of comment 16.

17. One comment asked whether FDA expects supplements to be submitted and approved and labeling changed within 1 year of publication of the final rule, or simply for supplements to be submitted within 1 year of publication of the final rule.

FDA expects supplements to be submitted and labeling to be changed within 1 year of publication of this final rule. Under current regulations (§ 314.70(c)) and the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 356a(b)), a manufacturer can file a changes being effected supplement for immediate implementation of this change. Thus, FDA believes implementation should take place in 1 year.

G. Cost of Implementing the Rule

FDA estimated in the proposed rule that the annualized cost to amino acid suppliers to implement the proposed rule would be $1,416,622. This figure includes first year or one-time costs estimated at $20 million.

18. One comment stated that wholesale raw material amino acids for intravenous use is a fraction of the $109 million market cited by FDA, and is actually much closer to $40 million. The comment went on to state that this market is shrinking and will continue to

[1] The clearance rate for aluminum is the rate at which aluminum is removed from the body by normal body functioning.

[2] Aluminum load is the amount of aluminum in the body.

do so for the foreseeable future. The comment estimated that, in light of these figures, the annual cost of compliance would represent 3 percent of sales, almost as much as the 4 percent spent by the industry on research and development. Another comment stated that the proposed rule underestimated the cost for compliance because validation without USP guidance would be difficult and because the number of worker hours required to test products is large.

FDA believes that the benefits of removing the health hazard outweigh costs to industry. FDA provides additional economic analysis based on these comments in section VII of this document.

19. The same comment stated that for LVP manufacturers, costs are even higher. The comment stated that the Eastern Research Group (ERG) study ''grossly underestimated the expense associated with label copy changes, non-compliant raw materials, finished product, and did not consider product recalls, which are inevitable, given the technically unfeasible 25 µg/L limit.''

FDA has reanalyzed these expenses in section VII of this document.

IV. Legal Authority

FDA's rule to regulate the aluminum content of certain parenteral drug products and to require aluminum content to be stated in the labeling of certain drug products is authorized by the Federal Food, Drug, and Cosmetic Act (the act). Section 502(a) of the act (21 U.S.C. 352(a)) prohibits false or misleading labeling of drugs, including, under section 201(n) of the act (21 U.S.C. 321(n)), failure to reveal material facts relating to potential consequences under customary conditions of use. Section 502(f) of the act requires drug labeling to have adequate directions for use, adequate warnings against use by patients where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration, as necessary to protect users. In addition, section 502(j) of the act prohibits the use of drugs that are dangerous to health when used in the manner suggested in their labeling. Drug products that do not meet the requirements of section 502 of the act are deemed to be misbranded.

In addition to the misbranding provisions, the premarket approval provisions of the act authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act (21 U.S.C. 355), FDA will approve a new drug application (NDA) only if the drug is shown to be safe and effective for its intended use under the conditions set forth in the drug's labeling. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the act.

Part 201 sets out FDA's general labeling regulations. Under § 201.100(d), prescription drug products must bear labeling that contains adequate information by which licensed practitioners can use the drugs safely and for their intended purposes. Section 201.57 describes specific categories of information, including information for drug use in selected subgroups of the general population and warnings on adverse reactions and potential safety hazards that must be present to meet the requirements of § 201.100. In addition, under 21 CFR 314.125, an NDA will not be approved unless there is adequate safety and effectiveness information for the labeled uses and the product complies with the requirements of part 201.

Any drug product not in compliance with § 201.323 is misbranded under section 502 of the act and an unapproved new drug under section 505 of the act.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a class of actions that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Implementation Plan

This final rule is effective on January 26, 2001. After that date, NDA's submitted under § 314.50 and abbreviated new drug applications (ANDA's) submitted under § 314.94 must comply with the labeling requirements under § 201.323. Holders of approved NDA's or ANDA's must meet the requirements of proposed § 201.323 by submitting supplements under § 314.70 or § 314.97. Applicants for LVP's used in TPN therapy and SVP's used as additives in TPN solutions are required to submit a supplement under § 314.70(c) that describes the assay method for determining the aluminum content. Applicants must submit validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment under § 314.60 or § 314.96.

VII. Analysis of Impacts

A. Introduction

FDA has examined the impact of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 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). The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities, if the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting 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 $100,000,000 (adjusted annually for inflation). The expected aggregate costs of this final rule, and the anticipated impact of the rule on small entities, are described in the analysis below. FDA concludes that this final rule is consistent with the regulatory philosophy and the principles set forth in the Executive Order and in these two statutes.

B. Compliance Requirements and Costs

In this final rule, FDA is amending its regulations by establishing a maximum permissible aluminum limit for LVP's used in TPN, as well as requiring certain label and package insert information for aluminum content in LVP's and SVP's used in TPN. The agency is issuing this rule to lower the risk of aluminum toxicity in light of evidence linking the use of parenteral drugs containing aluminum to morbidity and mortality among patients on TPN therapy. FDA estimates total annualized compliance costs for the final rule at about $23.8 million. Further, for reasons explained elsewhere in this section of the document, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. FDA has not identified any other Federal rules that duplicate, overlap, or conflict with this final rule.

In the preamble to the proposed rule, FDA relied on the report of its

contractor, ERG, for its estimates of compliance cost burdens of the proposed rule. Total annualized compliance costs were estimated at $20.1 million. This was composed of a one time cost of $63.8 million annualized at $9.8 million (over 10 years at a 7 percent discount rate) plus recurring annual costs of $10.3 million. Over 50 percent of the total costs would be due to actions undertaken to manufacture LVP solutions and their components that would comply with the aluminum limit requirements.

In response to the proposed rule, FDA received many comments, some of which referred to the cost estimates contained in the ERG report. As a result of these comments, ERG reanalyzed areas of concern specified in the comments and made some modifications to its original analysis of compliance costs. These changes are included in an addendum to the initial compliance cost analysis (available in the docket). As a result, FDA concludes that the final rule will impose annualized compliance costs of about $23.8 million on the affected industries, an increase of $3.7 million from its cost estimate for the proposed rule. This is composed of a one time cost of $67.3 million annualized at $10.6 million (over 10 years at a 7 percent discount rate) plus recurring annual costs of $13.2 million. The remainder of this section summarizes the addendum and responds to other comments concerning economic issues mentioned earlier in this preamble.

One comment to the proposal stated that FDA had underestimated the costs of label copy changes, noncompliant raw materials, finished product, and product recalls. As a result, ERG contacted industry to gain more information and data, where possible, to improve the accuracy of these estimates. ERG's new research into pharmaceutical labeling costs shows that compliance costs for the label changes, including inventory losses occurring at the changeover, are higher for this rule than previously estimated. Accordingly, FDA has increased its labeling change estimate to about $588,000 annually.

The original ERG report estimated compliance costs for final release testing for aluminum in finished LVP products and their raw material inputs at about $4.5 million annually. After subsequent discussions with industry, ERG recognized that some LVP production lots will fail to meet the required aluminum limit, but noted that this loss of finished product will be reduced by measures to lower the aluminum level of the raw material inputs. Similarly, ERG found that the cost of product recalls will be low due to the final release testing of LVP products, but it could not predict the likely frequency of such recalls.

The same comment also suggested that dextrose suppliers would incur compliance costs because some dextrose products contain aluminum at a level that might exceed the proposed limit. Upon further consideration of the possible existence of noncompliant raw materials, including dextrose and amino acids, and discussions between industry and ERG, FDA adjusted its original cost estimate to include an additional $2.72 million annually due to losses from noncompliant raw materials.

Another comment stated that FDA had underestimated laboratory assay method validation costs. Following ERG's review of its original analysis and further discussions with industry, FDA agrees with the comment as it relates to LVP manufacturers and has increased one-time assay method validation costs for this sector from $737,000 to $2.1 million. Further research into current compliance rates across all industry sectors, however, resulted in lowering assay method validation costs for some other sectors. The net result is a slight increase in total annualized assay method validation costs to about $1.72 million. Further, the estimate of annualized equipment purchase costs has been increased by $350,000.

Another comment referred to a statistic FDA used to show the relative size of the expected cost impact on amino acid suppliers. Specifically, the comment disagreed with the FDA statement that annual compliance costs for raw material amino acid suppliers would represent only 0.09 percent of sales, having been derived from $1.4 million in compliance costs and $1.6 billion in total amino acid sales. The comment proceeded with its own estimate of the relative size of the compliance cost for these suppliers, calculating it to be 3 1/2 percent of the $40 million in amino acid sales to TPN solution manufacturers, a level roughly equivalent to total research and development costs. Upon further analysis, FDA reaffirms its estimate of the average annual compliance cost per amino acid manufacturing establishment of about $1.4 million. However, because there are approximately nine supplier establishments, the total cost would be about $12.75 million, which equates to an even greater percentage of total sales of amino acids to TPN solution manufacturers, about 32 percent, than the comment suggested. The costs, nevertheless, amount to only about 0.09 percent of the total $1.6 billion in sales of amino acids to all industries as stated in the proposal.

As in its original analysis, ERG discussed but could not reliably forecast the likelihood that some suppliers of amino acids and possibly dextrose would abandon the TPN solution market, due to the relatively small percentage of total amino acid and dextrose sales to TPN manufacturers. Because the industry currently uses nine different suppliers, FDA does not anticipate product shortages. Nevertheless, the agency will remain alert to the possibility.

Any professional skills necessary for implementation of this final rule should already exist within the firms and should not need to be newly acquired.

C. Affected Entities

If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the significant economic impact of such a rule on small entities. In the proposed rule, FDA relied on the estimated compliance costs by type of establishment as projected by ERG. That analysis determined that very few of the affected companies are considered small by the standards of the Small Business Administration (SBA).[3] Therefore, the agency certified that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The agency received no comments specifically directed at this certification. Nevertheless, due to comments on other aspects of its estimates and modifications to the original analysis, FDA has reanalyzed the small business impacts of the final rule.

Fewer than 8 of the 24 companies identified in the ERG report as a manufacturer or supplier of TPN products or their inputs are small businesses according to the SBA definitions. No more than four SVP manufacturers are small under the SBA definitions. Moreover, since the average annualized cost for these establishments is estimated at about $51,000 each, the estimated annualized compliance costs for these companies are expected to account for less than one percent of their annual revenues. FDA further identified one amino acid supplier that may be a small business; but again, the annualized compliance costs for this firm would be less than 1 percent of annual revenues. The size of one dextrose supplier and one electrolyte

[3] SBA considers a small business in this context to be one with fewer than 750 employees (Ref. 2).

supplier could not be confidently determined due to the scarcity of data. Therefore, it was not possible to determine whether the compliance costs of these firms would represent more than 1 percent of their revenues. Based on the very few small firms that might incur a significant impact, the Commissioner of Food and Drugs certifies under section 605(b) of the Regulatory Flexibility Act that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

D. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before establishing any rule that requires expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation, or about $108 million in 1999) in any one year. The publication of this final rule concerning the regulation of TPN containing aluminum is not expected to result in expenditures of funds by State, local, or tribal governments, or the private sector in excess of $100 million annually. Because the agency estimates the largest 1-year expenditure to be about $80.5 million (representing the sum of one-time expenditures and annual expenditures), no further analysis is warranted according to the Unfunded Mandates Reform Act.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in this estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition.

Description: FDA is amending its regulations to add certain labeling requirements for aluminum content in LVP's, SVP's and PBP's used in TPN. FDA is also specifying an upper limit of aluminum permitted in LVP's and requiring manufacturers to submit to FDA for approval validated assay methods for determining aluminum content in parenteral drug products. The agency is adding these requirements because of evidence linking the use of parenteral drug products containing aluminum to morbidity and mortality among patients on TPN therapy, especially premature neonates and patients with impaired kidney function.

Based on data concerning the number of applications for LVP's, SVP's, and PBP's used in TPN received by the agency, FDA estimates that the labeling for approximately 200 products will be changed under § 201.323(b), (c), and (d). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each labeling change. Based on data collected by the Eastern Research Group (Ref. 1) concerning the number of affected manufacturers, FDA estimates that approximately 65 respondents will each submit one validated assay method annually under § 201.323(e). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each validated assay.

Description of Respondents: Persons and businesses, including small businesses and manufacturers.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
201.323(b), (c), (d)	200	1	200	14	2,800
201.323(e)	65	1	65	14	910
Total					3,710

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA did not receive any comments on the paperwork reduction aspects of the proposed rule.

The information collection provisions of this final rule have been submitted to OMB for review.

Before this rule becomes effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the information collection displays a current OMB control number.

IX. Federalism

FDA has analyzed this 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 federalism implications as defined in the order and, consequently, a Federalism summary impact statement is not required.

X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eastern Research Group, Addendum to Compliance Cost Analysis for a Regulation for Parenteral Drug Products Containing Aluminum, April 15, 1999.

2. U.S. Small Business Administration, Table of Size Standards, 1996.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.323 is added to subpart G to read as follows:

§ 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

(a) The aluminum content of large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN)

therapy must not exceed 25 micrograms per liter (μg/L).

(b) The package insert of LVP's used in TPN therapy must state that the drug product contains no more than 25 μg/L of aluminum. This information must be contained in the ''Precautions'' section of the labeling of all large volume parenterals used in TPN therapy.

(c) The maximum level of aluminum present at expiry must be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages (PBP's) used in the preparation of TPN solutions. The aluminum content must be stated as follows: ''Contains no more than—— μg/L of aluminum.'' The immediate container label of all SVP's and PBP's that are lyophilized powders used in the preparation of TPN solutions must contain the following statement: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than —— μg/L.'' This maximum level of aluminum must be stated as the highest of:

(1) The highest level for the batches produced during the last 3 years;

(2) The highest level for the latest five batches, or

(3) The maximum historical level, but only until completion of production of the first five batches after January 26, 2001.

(d) The package insert for all LVP's, all SVP's, and PBP's used in TPN must contain a warning statement. This warning must be contained in the ''Warnings'' section of the labeling. The warning must state:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 μg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

(e) Applicants and manufacturers must use validated assay methods to determine the aluminum content in parenteral drug products. The assay methods must comply with current good manufacturing practice requirements. Applicants must submit to the Food and Drug Administration validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment under § 314.60 or § 314.96 of this chapter.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1788 Filed 1–25–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Ractopamine Hydrochloride

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 (NADA) filed by Elanco Animal Health, A Division of Eli Lilly and Co. The NADA provides for use of a ractopamine hydrochloride Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. The regulations are also amended to provide for an acceptable daily intake (ADI) for ractopamine and tolerances for drug residues in edible products derived from treated swine.

DATES: This rule is effective January 26, 2000.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140–863 that provides for use of Paylean® (ractopamine hydrochloride) Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds must contain at least 16 percent crude protein. Feeds containing 4.5 grams per ton (g/t) ractopamine hydrochloride are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. Feeds containing 4.5 to 18 g/t ractopamine hydrochloride are used for improved feed efficiency and increased carcass leanness. The NADA is approved as of December 22, 1999, and the regulations in part 558 (21 CFR part 558) are amended by adding § 558.500 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Furthermore, § 558.4(d) is amended in the ''Category I'' table by adding an entry for ''ractopamine'' to provide for the assay limits for Type A medicated articles and Type B/C medicated feeds and the maximum Type B medicated feed level.

In addition, part 556 (21 CFR part 556) is amended by adding § 556.570 to establish an ADI for total ractopamine and tolerances for residues of ractopamine in edible tissues of treated swine.

In accordance with the freedom of information provisions of 21 CFR part and § 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 Dockets Management Branch (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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for food-producing animals qualifies for 5 years of marketing exclusivity beginning December 22, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved for any other application filed under section 512(b)(1).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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.