

COMMENTS ON DOCUMENT MANUAL—Continued

No.	Commenter	Manual ¶	Comment	Response
13	Enbridge, p. 10	12	With regard to the location of data in the headers and footers, clarify that if there is no specific instruction for the data's location, it may be placed in any location in the header.	See item 11 above.
14	Enbridge, p. 10; INGAA, App. A, pp. 7-8.	13	Clarify the meaning of "hard-keyed" headers or footers in tab-delimited or native format data files, and whether this requirement is applicable to headers and footers created by text programs such as Word.	Most native format data files and some spreadsheet files should not have hard-keyed headers or footers, as they disrupt the analysis and manipulation of the contents. The instruction is not relevant for text files, where the word processor normally manages headers and footers separate from the text content.
15	EEl, p. 14 PJM, p. 3	17	EEl notes that the last sentence is in error and should be deleted; whereas PJM is concerned about the implications this instruction may have with regard to access to its internal data.	EEl is correct, the last sentence should be struck. This moots PJM's concern.
16	EEl, p. 14 INGAA, App. A, p. 5-6.	28.d	Clarify the use and appearance of hyperlinks in an electronic document, and whether their use will result in a rejection of the filing.	The Commission clarifies that parties may not use hyperlinks as a means to include items as part of the record they intend to rely upon. Hyperlinks may be used as part of citations, and word processor conversions into hyperlinks were not the focus of this instruction.
17	INGAA, App. A, p. 3	passim	INGAA notes that the Commission's Part 154 electronic document instructions date from 1977[sic]. INGAA requests that those instructions be updated to reflect some of the flexibility offered by the new general instructions for electronic documents.	While beyond the scope of this proceeding, INGAA should contact the Secretary with a list of suggested changes and procedures.

[FR Doc. E7-22799 Filed 11-21-07; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Ractopamine

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 supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in two-way combination Type B and Type C medicated feeds containing ractopamine hydrochloride and monensin for cattle fed in confinement for slaughter.

DATES: This rule is effective November 23, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary

Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: daniel.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141 225 that provides for use of OPTAFLEXX (ractopamine hydrochloride) and RUMENSIN (monensin USP) Type A medicated articles to make dry and liquid two-way combination medicated feeds for cattle fed in confinement for slaughter. The supplemental NADA provides for an increased level of monensin in combination Type B and Type C medicated feeds. The supplemental NADA is approved as of October 30, 2007, and the regulations in 21 CFR 558.500 are amended to reflect the approval.

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.

The agency has determined under 21 CFR 25.33(a)(2) 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 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 Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.500, in the table in paragraph (e)(2), revise paragraphs (e)(2)(ii) and (e)(2)(vii) to read as follows:

§ 558.500 Ractopamine.

* * * * *
(e) * * *
(2) * * *

Ractopamine grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E zuernii</i> .	As in paragraph (e)(2)(i) of this section; see paragraph §§ 558.355(d) of this chapter.	000986
*	*	*	*	*
(vii) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E zuernii</i> .	As in paragraph (e)(2)(vi) of this section; see paragraph §§ 558.355(d) of this chapter.	000986
*	*	*	*	*

Dated: November 8, 2007.

Bernadette Dunham,
Deputy Director, Center for Veterinary Medicine.
[FR Doc. E7-22882 Filed 11-21-07; 8:45 am]
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9366]

RIN 1545-BG38

Notification Requirement for Tax-Exempt Entities Not Currently Required to File; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains a correction to temporary regulations (TD 9366) that was published in the **Federal Register** on Thursday, November 15, 2007 (72 FR 64147) describing the time and manner in which certain tax-exempt organizations not currently required to file an annual information return under section 6033(a)(1) are required to submit an annual electronic notice including certain information required by section 6033(i)(1)(A) through (F).

DATES: The correction is effective November 23, 2007.

FOR FURTHER INFORMATION CONTACT: Monice Rosenbaum at (202) 622-6070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction are under section 6033 of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (TD 9366) contain an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the temporary regulations (TD 9366), which was the subject of FR Doc. E7-22299, is corrected as follows:

On page 64149, column 1, second paragraph of the column, in the preamble, under the paragraph heading “*Organizations Required To File Returns or Submit Electronic Notice*”, line 5, the language “an organization exemption from” is corrected to read “an organization exempt from”.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).
[FR Doc. E7-22892 Filed 11-21-07; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Department of the Navy, Chesapeake Bay, in Vicinity of Bloodsworth Island, MD

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Final rule.

SUMMARY: The Corps of Engineers is amending its regulations to modify an existing danger zone, in waters of the United States in the vicinity of Bloodsworth Island, Maryland. The amendment reflects the current operational and safety procedures at the Bloodsworth Island Range and highlights a change in the enforcement authority from the Commander, Naval Base Norfolk, Virginia to the Commander, Naval Air Station Patuxent River, Maryland. The regulations are necessary to safeguard United States Navy vessels and United States Government facilities/installations from sabotage and other subversive acts, accidents, or incidents of a similar nature. These regulations are also necessary to protect the public from potentially hazardous conditions which may exist as a result from use of the areas by the United States Navy.

DATES: *Effective Date:* December 24, 2007.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW-CO (David B. Olson), 441 G Street, NW., Washington, DC 20314-1000.