substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9H, *Airspace Designations and Reporting Points,* dated September 1, 2000, and effective September 16, 2000, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Indian Mountain, AK [New]

Indian Mountain LRRS, AK

(lat. 65° 59′ 34″ N., long. 153° 42′ 16″ W.)

That airspace extending upward from 700 feet above the surface within a 4 mile radius of Indian Mountain LRRS; and that adjacent airspace extending upward from 1,200 feet above the surface from lat. 66° 00′ 00″ N long. 154° 05′ 00″ W, to lat. 66° 00′ 00″ N long. 153° 00′ 00″ W, to lat. 66° 09′ 00″ N long. 153° 00′ 00″ W, to lat. 66° 09′ 00″ N long. 153° 40′ 00″ W, to lat. 66° 06′ 00″ N long. 154° 00′ 00″, thence to the point of the beginning, excluding the existing Class E airspace.

* * * * *

Issued in Anchorage, AK, on January 2, 2001.

Stephen P. Creamer,

Acting Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 01–701 Filed 1–9–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 98N–0720]

Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for applications for FDA approval to market a new drug to correct inadvertent errors. This action is necessary to ensure the accuracies and consistency of the regulation.

DATES: This rule is effective January 16, 2001.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 1999 (64 FR 396), FDA published a direct final rule that removed from the agency's regulations references to the now-repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs (conforming regulation). Section 314.430(f) (21 CFR 314.430(f)) provides that safety and effectiveness data and information in an application may be disclosed to the public when certain events happen. Prior to the conforming regulation, § 314.430(f)(6) read: ''For applications or abbreviated applications submitted under sections 505(j) and 507 of the act, when FDA sends an approval letter to the applicant''.

The conforming regulation inadvertently changed ''section 505(j)'' to ''section 505'' and failed to remove the word ''applications'' from the introductory clause the first time it appeared. This document corrects those errors. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

§ 314.430 [Amended]

2. Section 314.430 *Availability for public disclosure of data and information in an application or abbreviated application* is amended in paragraph (f)(6) by removing ''applications or'' and by removing ''505'' and adding in its place ''505(j)''.

Dated: January 4, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–680 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Decoquinate, Monensin, and Tylosin

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 Alpharma, Inc. The NADA provides for use of approved, single-ingredient decoquinate, monensin, and tylosin Type A medicated articles to make three-way combination drug Type B and Type C medicated feeds used for prevention of coccidiosis, improved feed efficiency, and reduction of incidence of liver abscesses in growing-finishing cattle fed in confinement for slaughter.

DATES: This rule is effective January 10, 2001.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–149 that provides for use of DECCOX® (27.2 gram per pound (g/lb) decoquinate), Rumensin® (20, 30, 45, 60, 80, or 90.7 g/lb monensin activity as monensin sodium) and TYLAN® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make three-way combination Type B and Type C medicated feeds for use in growing-finishing cattle fed in confinement for slaughter. The Type C medicated feeds contain 13.6 to 27.2 g/ton decoquinate, 5 to 30 g/ton monensin, and 8 to 10 g/ton tylosin, and are used for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, improved feed efficiency, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*. The NADA is approved as of November 16, 2000, and the regulations in 21 CFR 558.195 and 558.625 are being amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 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.

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 an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 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. Section 558.195 is amended in the table in paragraph (d) by adding an entry after ''Monensin 5 to 30'' and before ''Chlortetracycline approximately 400'' to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
	Monensin 5 to 30; plus tylosin 8 to 10	Cattle fed in confinement for slaughter; for prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, improved feed efficiency, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*.	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see (c)(1) of this paragraph and § 558.355(d)(8). Monensin as monensin sodium and tylosin as tylosin phosphate provided by 000986 in § 510.600(c) of this chapter.	046573
*	*	* *	* *	*

§ 558.355 [Amended]

3. Section 558.355 *Monensin* is amended in paragraph (f)(7) by adding ''alone or with tylosin'' after ''decoquinate''.

4. Section 558.625 is amended by redesignating paragraphs (f)(2)(i) through (f)(2)(v) as (f)(2)(ii) through (f)(2)(vi), and by adding paragraph (f)(2)(i) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(i) Decoquinate and monensin as in § 558.195.

* * * * *

Dated: December 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–628 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 640

[Docket No. 98N–0673]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Confirmation in Part and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation in part and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is confirming in part the direct final rule issued in the **Federal Register** of August 19, 1999. The direct final rule amends 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. FDA is confirming the provisions for which no significant adverse comments were received. The agency received significant adverse comments on certain provisions and is amending Title 21 Code of Federal Regulations to reinstate the former provisions.

DATES: The effective date for the amendments to the sections published in the **Federal Register** of August 19, 1999 (64 FR 45366), and listed in table 1 of this document, is confirmed as February 11, 2000. The amendments listed in table 2 of this document are effective January 10, 2001.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: Written comments concerning the direct final rule were to be submitted on or before December 3, 1999. FDA stated that the effective date of the direct final rule would be February 11, 2000. If no timely significant comments were submitted to FDA during the comment period, FDA intended to publish a document in the **Federal Register** within 30 days after the comment period ended, confirming the effective date of the final rule. If timely significant comments were received, the agency intended to publish a document in the **Federal Register** withdrawing the direct final rule before its effective date. Because of complex issues related to this rulemaking and because of competing priorities, FDA did not issue a document either confirming or withdrawing the direct final rule before its effective date. Therefore the Code of Federal Regulations was revised as of April 1, 2000, to codify the regulations in the direct final rule.

The agency received significant comments to the docket. If a significant adverse comment applies to an amendment, paragraph, or section of the rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

Thus, FDA is confirming in part the direct final rule (sections listed in table 1 of this document) effective February 11, 2000.

The agency is making technical amendments to 21 CFR 640.25(c), 640.56(c), and 640.71(a) by replacing ''Clinical Laboratories Improvement Act of 1967 (CLIA)'' with ''Clinical Laboratories Improvement Amendments of 1988 (CLIA).'' This action is necessary for consistency when referring to CLIA in the regulations.

TABLE 1.—AMENDMENTS EFFECTIVE FEBRUARY 11, 2000

21 CFR Section	Action
606.3(c), (e), and (f)	Revised.
606.100(b) and (d)	Revised introductory text.
606.100(b)(7) and (b)(18)	Revised.
606.121(a), (d)(2), and (e)(1)(ii)	Revised.
606.122(f) and (n)(4)	Revised.
606.151(e)	Revised.
606.160(b)(2)(v)	Revised.
606.170(b)	Revised.
640.2(b) and (d)	Removed.
640.2(c), (e), and (f)	Redesignated as (b), (c), and (d).
640.2(c)(2)	Revised.
640.3(b)	Revised introductory text.
640.3(b)(3), (c)(2), and (c)(3)	Revised.
640.3(e)	Removed and reserved.
640.4(d)(1) through (d)(4), and (h)	Removed.
640.4(i)	Redesignated as paragraph (h).
640.4(b) and (d)	Revised.
640.6(c)	Removed.
640.13(a)	Revised.
640.16(b)	Revised.
640.22(a)	Revised.
640.25(c)	Nomenclature change.
640.31(c)	Removed.