

amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (Air).

Issued in Washington, DC on September 18, 1998.

Richard O. Gordon,

Acting Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective October 8, 1998*

Tampa, FL, Vandenberg, GPS RWY 18, Amdt 1

Tampa, FL, Vandenberg, GPS RWY 23, Orig
Terre Haute, IN, Terre Haute International-Hulman Field, VOR/DME RNAV RWY 32, Amdt 8

Lakeview, MI, Lakeview Airport-Griffith Field, VOR/DME RWY 9, Orig

Albermarle, NC, Stanly County, LOC RWY 22L, ORIG-E, CANCELLED

Albermarle, NC, Stanly County, ILS RWY 22L, ORIG

Charlotte, NC, Charlotte/Douglas Intl, LOC BC RWY 23, Amdt 10A, CANCELLED
Charlotte, NC, Charlotte/Douglas Intl, ILS RWY 23, ORIG

Charlotte, NC, Charlotte/Douglas Intl, VOR/DME RNAV RWY 23, ORIG, CANCELLED
Athens/Albany, OH, Ohio University, LOC RWY 25, Amdt 3A, CANCELLED

Athens/Albany, OH, Ohio University, ILS RWY 25, Orig

Columbia, SC, Columbia Metropolitan, ILS RWY 11, Amdt 14

Grand Prairie, TX, Grand Prairie Muni, VOR/DME RWY 35, Orig

Grand Prairie, TX, Grand Prairie Muni, GPS RWY 35, Orig
Seattle, WA, Seattle-Tacoma Intl, ILS RWY 16L, ORIG
Seattle, WA, Seattle-Tacoma Intl, ILS/DME RWY 34R, Amdt 1

* * * *Effective November 5, 1998*

Liberal, KS, Liberal Muni, VOR/DME OR GPS RWY 17, Amdt 3

Chester, SC, Chester Muni, NDB RWY 35, Orig

* * * *Effective December 3, 1998*

Borrego Springs, CA, Borrego Valley, GPS RWY 25, Orig

Dunnellon, FL, Dunnellon, GPS RWY 23, Orig

Tupelo, MS, Tupelo Municipal-C D Lemons, GPS RWY 18, Orig

Tupelo, MS, Tupelo Municipal-C D Lemons, GPS RWY 36, Orig

Missoula, MT, Missoula International, GPS-D

Missoula, MT, Missoula International, GPS RWY 11, Orig

Plattsmouth, NE, Plattsmouth Muni, NDB RWY 34, Amdt 4

Plattsmouth, NE, Plattsmouth Muni, GPS RWY 16, Orig

Plattsmouth, NE, Plattsmouth Muni, GPS RWY 34, Orig

Crosby, ND, Crosby Muni, GPS RWY 30, Orig
Lewisburg, WV, Greenbrier Valley, VOR RWY 4, Orig

Lewisburg, WV, Greenbrier Valley, NDB RWY 4, Amdt 5

Lewisburg, WV, Greenbrier Valley, ILS RWY 4, Amdt 8

Lewisburg, WV, Greenbrier Valley, VOR RWY 22, Orig

Note: The FAA published an Amendment in Docket No. 29328, Amdt. No. 1888 to Part 97 of the Federal Aviation Regulations (63 FR 49002; dated September 14, 1998) under § 97.23 effective October 8, 1998, which is hereby amended by rescinding the following procedures:

Boise, ID, Boise Air Terminal/Gowen Field, VOR/DME OR TACAN RWY 10L, Orig
Boise, ID, Boise Air Terminal/Gowen Field, NDB RWY 10L, Orig

[FR Doc. 98-25873 Filed 9-28-98; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Streptomycin Oral Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect

approval of an abbreviated new animal drug application (ANADA) filed by Contemporary Products, Inc. The ANADA provides for the use of streptomycin oral solution in drinking water for the treatment of nonspecific infectious enteritis in chickens and for the treatment of bacterial enteritis in swine and calves.

EFFECTIVE DATE: September 29, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION:

Contemporary Products, Inc., 3788 Elm Springs Rd., P.O. Box 6067, Springdale, AR 72766-6067, filed ANADA 200-197 that provides for the use of streptomycin oral solution in drinking water for the treatment of nonspecific infectious enteritis in chickens and for the treatment of bacterial enteritis in swine and calves.

Contemporary Products, Inc.'s ANADA 200-197 is approved as a generic copy of Veterinary Services, Inc.'s NADA 065-252. ANADA 200-197 is approved as of August 3, 1998, and the regulations are amended in 21 CFR 520.2158a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Contemporary Products, Inc., is not currently listed in the animal drug regulations as the sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) are amended by adding a new listing for the sponsor.

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)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Contemporary Products, Inc." and in

the table in paragraph (c)(2) by numerically adding a new entry for "055462" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address					Drug labeler code
*	*	*	*	*	*
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764-6067					055462
*	*	*	*	*	*

(2) * * *

Drug labeler code	Firm name and address				
*	*	*	*	*	*
055462	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764-6067				
*	*	*	*	*	*

PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.2158a [Amended]

4. Section 520.2158a *Streptomycin sulfate oral solution* is amended in paragraph (b) by removing the phrase "No. 033008" and adding in its place "Nos. 033008 and 055462".

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-25904 Filed 9-28-98; 8:45 am]

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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Fujisawa USA, Inc., to American Pharmaceutical Partners, Inc.

EFFECTIVE DATE: September 29, 1998.

FOR FURTHER INFORMATION CONTACT:

Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Fujisawa USA, Inc., Deerfield, IL 60015-2548, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 100-840 (Chorionic Gonadotropin) to American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160. Accordingly, the agency is amending the regulations in 21 CFR 510.600 and 522.1081 to reflect the transfer of ownership. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Fujisawa USA, Inc., because the firm is no longer the sponsor of any approved NADA's, and by alphabetically adding a new listing for American Pharmaceuticals Partners, Inc.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Fujisawa USA, Inc.," and by alphabetically adding an entry for "American Pharmaceutical Partners, Inc.," and in the table in paragraph (c)(2) by removing the entry for "000469" and by numerically adding an entry for "063323" to read as follows: