

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the "Food Chemicals Codex," 4th ed. (1996), pp. 760-761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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17. Section 184.1979b is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote number "1" to read as follows:

§ 184.1979b Reduced minerals whey.

* * * * *

(b) * * *

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at

the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the "Food Chemicals Codex," 4th ed. (1996), pp. 760-761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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18. Section 184.1979c is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote numbers "1" and "2" to read as follows:

§ 184.1979c Whey protein concentrate.

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(b) * * *

(1) The analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the "Food Chemicals Codex," 4th ed. (1996), pp. 760-761, which is incorporated by reference in accordance

with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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Dated: December 7, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-563 Filed 1-11-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clomipramine Hydrochloride Tablets

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 Novartis Animal Health US, Inc. The NADA provides for oral veterinary prescription use of clomipramine hydrochloride tablets to be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

EFFECTIVE DATE: January 12, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-120 that provides for oral veterinary prescription administration of Clomicalm™ (clomipramine hydrochloride) tablets at 2 to 4 milligrams (mg)/kilogram body weight per day (0.9 to 1.8 mg per pound per day) administered as a single daily dose or divided twice daily to dogs greater than 6 months of age. The NADA is approved as of December 10, 1998, and the regulations are amended in 21 CFR

part 520 by adding new § 520.455 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.

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 qualifies for a 5-year period of marketing exclusivity beginning December 10, 1998, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

FDA has determined under 21 CFR 25.33(d)(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 in 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

2. Section 520.455 is added to read as follows:

§ 520.455 Clomipramine hydrochloride tablets.

(a) *Specifications.* Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use.* For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 4, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99-639 Filed 1-11-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98N-0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of September 29, 1998 (63 FR 51825), a direct final rule and a correction document published in the

Federal Register of November 27, 1998 (63 FR 65554). The direct final rule amends certain regulations that govern establishment registration and device listing by domestic distributors. This document confirms the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule published at 63 FR 51825 is confirmed as February 11, 1999.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ-305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20857, 301-594-4699.

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending on December 14, 1998. FDA stated that the effective date of the direct final rule would be on February 11, 1999, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comment. The direct final rule contained no information collection. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3502) was not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing were filed in response to the September 29, 1998, final rule. Accordingly, the amendments issued thereby are effective on February 11, 1999.

Dated: January 4, 1999.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

[FR Doc. 99-565 Filed 1-11-99; 8:45 am]

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