DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 75N-0244]

New Drugs; Drugs for Human Use; Over-the-Counter (OTC) Daytime Sedatives; Correction

AGENCY: Food and Drug Administration.

ACTION: Final order; correction.

SUMMARY: In FR Doc. 79-19448 appearing at page 36378 in the Federal Register of June 22, 1979, the following correction is made in the listing of claims that have been made for daytime sedative products: In § 310.519(a) appearing at page 36380, "nervous headache" is changed to read "nervous tension headache."

FOR FURTHER INFORMATION CONTACT: Agnes Black, Federal Register Writer (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

Dated: July 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-21003 Filed 7-14-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 522

Colloidal Ferric Oxide Injection; Revocation of Certain Regulations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is revoking that portion of the regulations reflecting approval of a new animal drug application (NADA) providing for use of colloidal ferric oxide injection for use in baby pigs for the prevention and treatment of anemia due to iron deficiency. The sponsor, Norden Laboratories, requested the withdrawal of approval.

EFFECTIVE DATE: July 25, 1980.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, approval of NADA 15-035 is withdrawn. This document amends the regulations to delete that portion which reflects approval of this NADA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), Part 522 is amended.

§ 522.940 [Amended]

Amend § 522.940 *Colloidal ferric oxide injection* by deleting in paragraph (b) the sponsor number "011519."

Effective date. July 25, 1980.

(Sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e)))

Dated: July 2, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80-20854 Filed 7-14-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 524

Chlorhexidine Diacetate Ointment; NAS/NRC Update

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations for chlorhexidine diacetate ointment to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data. These conditions of use were classified as effective as a result of a National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group evaluation of the product. In lieu of certain effectiveness data, approval may require submission of bioequivalence or similar data. A previous Federal Register publication has reflected that this product is in compliance with the conclusions of the review.

EFFECTIVE DATE: July 15, 1980.

FOR FURTHER INFORMATION CONTACT: Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: The NAS/NRC review of this product was published in the Federal Register of July 17, 1970 (35 FR 11533). In that document, the Academy concluded, and FDA concurred, that the product was probably effective as a topical ointment.

That announcement was issued to inform holders of new animal drug applications (NADA's) of the findings of the Academy and the agency, and to inform all interested persons that such articles could be marketed if they were the subject of approved NADA's and otherwise complied with the requirements of the Federal Food, Drug, and Cosmetic Act.

Fort Dodge Laboratories, Fort Dodge, IA 50501 responded to the notice by submitting a supplemental NADA (9-782V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the product in horses, dogs, and cats as a topical antiseptic ointment. The supplemental application was approved by a regulation published in the Federal Register of May 1, 1973 (38 FR 10714). The regulation reflecting this approval established a new section for the drug in 21 CFR 135a.35, recodified at 21 CFR 524.402. The new section did not specify those conditions of use that were NAS/NRC approved.

This document amends the regulations to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data required for approval by § 514.111(a)(5)(ii)(*a*)(*4*) of the new animal drug regulations. In lieu of those data, approval of applications for such products may be obtained if bioequivalency or similar data are submitted as suggested in the guideline for submitting NADA's for generic drugs reviewed by the NAS/NRC. The guideline is available from the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 524 is amended in § 524.402 by adding after paragraph (c)(1), (2), and (3) the footnote reference [1] and by adding at the end of the section the footnote to read as follows:

§ 524.402 Chlorhexidine diacetate ointment.

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(c) *Conditions of use.* (1) * * * [1]

(2) * * * [1]

(3) * * * [1]

Effective date. This regulation shall be effective July 15, 1980.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.