Exchange	Type of contract	FR date and citation
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[FR Doc. 89-28456 Filed 12-5-89; 8:45 am]
BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N-0419]

RIN 0905-AA06

Aphrodisiac Drug Products for Over-the-Counter Human Use; Final Rule; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; clarification.

SUMMARY: The Food and Drug Administration (FDA) is issuing a clarification of its final rule establishing that any aphrodisiac drug product for over-the-counter (OTC) human use is not generally recognized as safe and effective and is misbranded (July 7, 1989; 54 FR 28780). In discussing the impact of this final rule on the marketing of aphrodisiac drug products, the agency stated in the preamble to the final rule that "On or after January 8, 1990, no OTC drug products that are subject to this final rule may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA)." (See 54 FR 28780.) In order to avoid a possible misunderstanding of the intent of this language, FDA is adding another sentence, immediately after the above statement, for clarification. Thus, aphrodisiac drug products already in interstate commerce on the effective date of this final rule that are subsequently relabeled or repackaged will be regarded as a new product introduced into interstate commerce and, hence, in violation of the Federal Food, Drug, and Cosmetic Act.

DATES: Written comments on the clarification by January 5, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301-295-8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 15954, appearing on page 28780, second column, in the **Federal Register** of Friday, July 7, 1989, the following sentence is added to the second complete paragraph, after the second sentence under **"SUPPLEMENTARY INFORMATION"** to read as follows: "Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective date of this final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce."

Dated: November 28, 1989.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-28391 Filed 12-5-89; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 310

[Docket No. 80N-0357]

RIN 0905-AA06

Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use; Final Rule; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; clarification.

SUMMARY: the Food and Drug Administration (FDA) is issuing a clarification of its final rule establishing that any over-the-counter (OTC) hair grower or hair loss prevention drug product for external use is not generally recognized as safe and effective and is misbranded (July 7, 1989; 54 FR 28772). In discussing the impact of this final rule on the marketing of hair grower and hair loss prevention drug products, the agency stated in the preamble to the final rule that "On or after January 8, 1990, no OTC drug products that are subject to this final rule may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA)." (See 54 FR 28772.) In order to avoid a possible misunderstanding of the intent of this language, FDA is adding another sentence, immediately after the above statement, for clarification. Thus, hair grower or hair loss prevention drug products already in interstate commerce on the effective date of this final rule that are subsequently relabeled or repackaged will be regarded as a new product introduced into interstate commerce and, hence, in violation of the Federal Food, Drug, and Cosmetic Act.

DATES: Written comments on the clarification by January 5, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 89-15955, appearing on page 28772, second column, in the **Federal Register** of Friday, July 7, 1989, the following sentence is added to the second complete paragraph, after the last sentence under **"SUPPLEMENTARY INFORMATION"** to read a follows: "Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective date of this final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce."

Dated: November 28, 1989.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-28392 Filed 12-5-89; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Detomidine Hydrochloride Injection

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 Farmos Group, Ltd., providing for the safe and effective use of Dormosedan™ (detomidine hydrochloride) injection as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

EFFECTIVE DATE: December 6, 1989.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine, Food and Drug