

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

Display Date	3-30-01
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Certifier	Monique Oliver

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 abbreviated new animal drug application (ANADA) from Inhalon Pharmaceuticals, Inc., to Minrad, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

SUPPLEMENTARY INFORMATION: Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002, has informed FDA that it has transferred to Minrad, Inc., 836 Main St., 2d floor, Buffalo, NY 14202, ownership of, and all rights and interests in, ANADA 200-141 for Isoflurane, USP. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) and § 529.1186 (21 CFR 529.1186) to reflect the transfer of ownership.

In addition, Minrad, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, § 510.600(c) is being amended to add entries for the firm. Since Inhalon Pharmaceuticals, Inc., no longer is the sponsor of any approved new animal drug application, their drug labeler code (060307) is being reassigned to Minrad, Inc., as requested. This drug labeler code was removed from § 529.1186(b) in error (60 FR 40455, August 9, 1995), and it is being added at this time.

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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

21 CFR Part 510

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

21 CFR Part 529

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 529 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 "Inhalon Pharmaceuticals, Inc.," and by alphabetically adding an entry for "Minrad, Inc.," and in the table in paragraph (c)(2) by revising the entry for "060307" 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
Minrad, Inc., 836 Main St., 2d floor, Buffalo, NY 14202	060307

(2) * * *

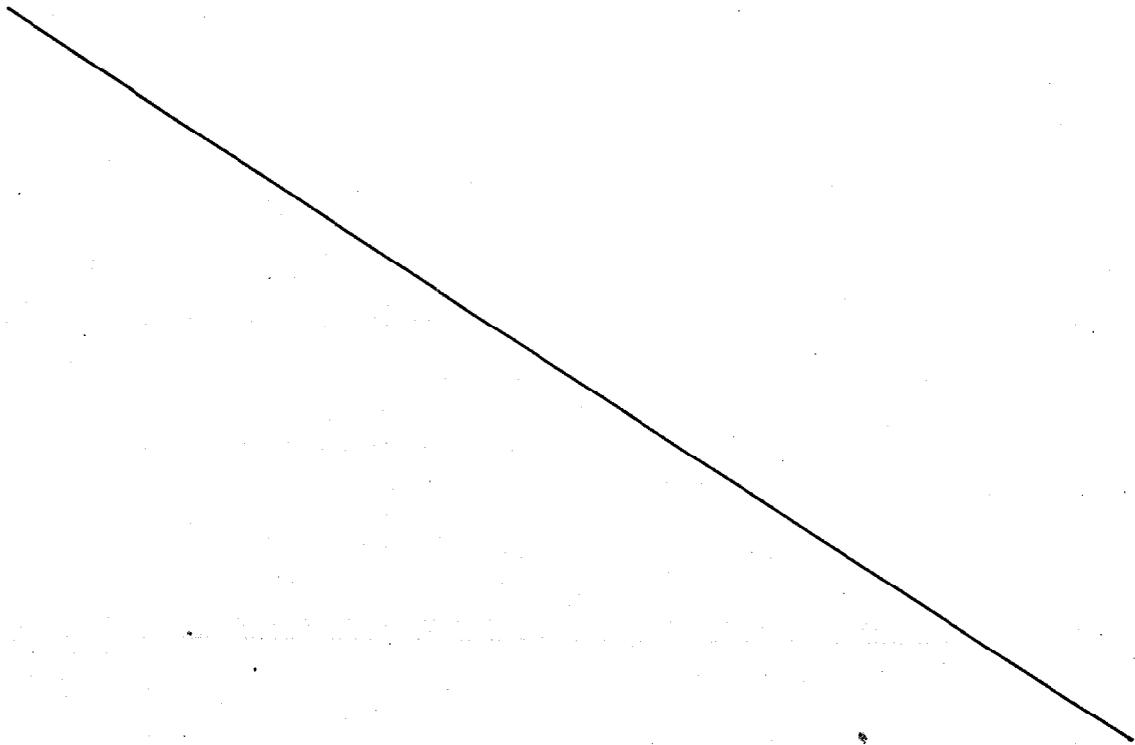
Drug labeler code	Firm name and address
060307	Minrad, Inc., 836 Main St., 2d floor, Buffalo, NY 14202

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1186 [Amended]



4. Section 529.1186 *Isoflurane* is amended in paragraph (b) by removing “and 059258” and adding in its place “059258, and 060307”.

Dated: March 2, 2001

March 2, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Romane Oliver

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