

367. An applicant must apply to receive all business proprietary information on the record of the segment of a proceeding in question, but may waive service of business proprietary information it does not wish to receive from other parties to the proceeding. An applicant must serve an APO application on the other parties by the most expeditious manner possible at the same time that it files the application with the Department.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Change of Sponsor's Address

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 address for Huvepharma AD, a sponsor of approved new animal drug applications.

DATES: This rule is effective July 6, 2011.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, e-mail: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria, has informed FDA that it has changed its address to 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect this change.

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 in 21 CFR Part 510

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

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 510 is 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. In § 510.600, in the table in paragraph (c)(1), revise the entry for "Huvepharma AD"; and in the table in paragraph (c)(2), revise the entry for "016592" to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Table with 2 columns: Firm name and address, Drug labeler code. Row 1: Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria, 016592

(2) * * *

Table with 2 columns: Drug labeler code, Firm name and address. Row 1: 016592, Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria.

Dated: June 24, 2011.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 48

[TD 9533]

RIN 1545-BK28

Modification of Treasury Regulations Pursuant to Section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations that remove any reference to, or requirement of reliance on, "credit ratings" in regulations under the Internal Revenue Code (Code) and provides substitute standards of credit-worthiness where appropriate. This action is required by the Dodd-Frank Wall Street Reform and Consumer Protection Act, which requires Federal agencies to remove any reference to, or requirement of reliance on, credit ratings from their regulations and to substitute such standard of credit-worthiness as the agency deems appropriate for such regulations. These regulations affect persons subject to various provisions of the Code. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the Federal Register.

DATES: Effective Date: These regulations are effective on July 6, 2011.

Applicability Dates: For dates of applicability, see §§ 1.150-1T(a)(4), 1.171-1T(f), 1.197-2T(b)(7), 1.249-1T(f)(3), 1.475(a)-4T(d)(4), 1.860G-2T(g)(3), 1.1001-3T(d), (e), and (g), and 48.4101-1T(l)(5).

FOR FURTHER INFORMATION CONTACT: Arturo Estrada, (202) 622-3900 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 939A(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203 (124 Stat. 1376 (2010)), (the "Dodd-Frank Act"), requires each Federal agency to review its regulations that require the use of an assessment of credit-worthiness of a security or money market instrument, and to review any references or requirements in those regulations regarding credit ratings. Section 939A(b) directs each agency to