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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name and 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 sponsor name and address from DuPont Pharmaceuticals to DuPont Merck Pharmaceutical Co.

EFFECTIVE DATE: February 8, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: DuPont Pharmaceuticals, One Rodney Square, Wilmington, DE 19898, has informed FDA of a change of sponsor name and address to DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name and address.

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: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (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 ''DuPont Pharmaceuticals '' and by alphabetically adding a new entry for ''DuPont Merck Pharmaceutical Co.,'' and in the table in paragraph (c)(2) in the entry for ''000056'' by revising the sponsor name and address 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
* * * *	* * *
DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805.	000056
* * * *	* * *

(2)* * *

Drug labeler code	Firm name and address
* * * *	* * *
000056	DuPont Merck Pharmaceuticals Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805
* * * *	* * *

Dated: February 1, 1996.

Robert C. Livingston,

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

[FR Doc. 96–2688 Filed 2–7–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–5418–3]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency.

ACTION: Notice of acceptability and clarification of June 13, 1995 final rule.

SUMMARY: This notice expands the list of acceptable substitutes for ozone-depleting substances (ODS) under the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program. SNAP implements section 612 of the amended Clean Air Act of 1990, which requires EPA to evaluate substitutes for the OZONE-DEPLETING SUBSTANCES (ODS), and regulate the use of substitutes where other alternatives exist that reduce overall risk to human health and the environment. Through these evaluations, SNAP generates lists of acceptable and unacceptable substitutes for each of the major industrial use sectors. In addition, this Notice clarifies several points from the June 13, 1995 final rule (60 FR 31092).

On March 18, 1994, EPA promulgated its plan for administering the SNAP program, and issued decisions on the acceptability and unacceptability of a number of substitutes (59 FR 13044). In today's Notice, EPA issues decisions on the acceptability of substitutes not previously reviewed by the Agency. The intended effect of this action is to expedite movement away from ozone depleting compounds. To arrive at determinations on the acceptability of substitutes, the Agency completed a cross-media sector end-use screening assessment of risks to human health and the environment.

EFFECTIVE DATE: February 8, 1996.

ADDRESSES: Information relevant to this notice is contained in Air Docket A–91–42, Central Docket Section, South Conference Room 4, U.S. Environmental Agency, 401 M Street SW., Washington, DC 20460. Telephone: (202) 260–7548. The docket may be inspected between 8 a.m. and 5:30 p.m. weekdays. As provided in 40 CFR part 2, a reasonable fee may be charged for photocopying.

FOR FURTHER INFORMATION CONTACT: Jeffrey Levy at (202) 233–9727 or fax (202) 233–9577, U.S. EPA, Stratospheric Protection Division, 401 M Street, SW., Mail Code 6205J, Washington, DC 20460; EPA Stratospheric Ozone Protection Hotline at (800) 296–1996; EPA World Wide Web Site at http://www.epa.gov/docs/ozone/title6/SNAP/snap.html.

SUPPLEMENTARY INFORMATION:

I. Section 612 Program

A. Statutory Requirements

Section 612 of the Clean Air Act authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances. EPA is referring to this program as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

- *Rulemaking*—Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, methyl bromide, and hydrobromofluorocarbon) or class II (hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.
- *Listing of Unacceptable/Acceptable Substitutes*—Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. EPA must publish a corresponding list of acceptable alternatives for specific uses.
- *Petition Process*—Section 612(d) grants the right to any person to petition EPA to add a substance to or delete a substance from the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional 6 months.
- *90-day Notification*—Section 612(e) requires EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or *existing* chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.
- *Outreach*—Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.
- *Clearinghouse*—Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. Regulatory History

On March 18, 1994, EPA published the Final Rulemaking (FRM) (59 FR 13044) which described the process for administering the SNAP program and issued EPA's first acceptability lists for substitutes in the major industrial use sectors. These sectors include: refrigeration and air conditioning; foam blowing; solvent cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors compose the principal industrial sectors that historically consumed the largest volumes of ozone-depleting compounds.

As described in the final rule for the SNAP program (59 FR 13044), EPA does not believe that rulemaking procedures are required to list alternatives as acceptable with no limitations. Such listings do not impose any sanction, nor do they remove any prior license to use a substance. Consequently, EPA is adding substances to the list of acceptable alternatives without first requesting comment on new listings.

EPA does, however, believe that notice-and-comment rulemaking is required to place any substance on the list of prohibited substitutes, to list a substance as acceptable only under certain conditions, to list substances as acceptable only for certain uses, or to remove a substance from either the list of prohibited or acceptable substitutes. Updates to these lists are published as separate notices of rulemaking in the Federal Register.

The Agency defines a ''substitute'' as any chemical, product substitute, or