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(Catalog of Federal Domestic Assistance Program Nos. 96.001 Social Security—Disability Insurance; 96.002 Social Security—Retirement Insurance; 96.004 Social Security—Survivors Insurance; 96.006 Supplemental Security Income)

List of Subjects in 20 CFR Part 422

Administrative practice and procedure; Freedom of information; Organization and functions (Government agencies); Social Security.

Dated: June 14, 1995.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set out in the preamble, Subpart B of Part 422 of 20 CFR Chapter III is amended as follows:

PART 422—ORGANIZATION AND PROCEDURES

1. The authority citation for Subpart B is revised to read as follows:

Authority: Secs. 205, 702, and 1143 of the Social Security Act; 42 U.S.C. 405, 902, and 1320b-13.

2. Section 422.107 is amended by adding language at the end of paragraph (c), to read as follows:

§ 422.107 Evidence requirements.

(c) *Evidence of identity.* * * * An applicant for a duplicate social security number card who is a U.S. citizen and who resides in an area where the Social Security Administration is conducting a pilot project on the issuance of duplicate cards will not be required to submit a signed application or corroborative documentary evidence of identity if the Social Security Administration is able to compare information provided by the applicant with information already in its records and, on the basis of this comparison, decides that corroborative documentary evidence is not needed to establish the applicant's identity. These special procedures do not apply to foreign-born U.S. citizens who have not already submitted evidence of citizenship to us; to a person applying on behalf of another if the applicant is not a parent applying on behalf of his or her minor

child; and to people whose address is an in-care-of address, a post office box, general delivery, or a suite.

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[FR Doc. 95-15301 Filed 6-21-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

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 46 new animal drug applications (NADA's) from Sanofi Animal Health, Inc., to Rhone Merieux, Inc.

EFFECTIVE DATE: June 22, 1995.

FOR FURTHER INFORMATION CONTACT:

Judith M. O'Haro, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1737.

SUPPLEMENTARY INFORMATION: Sanofi Animal Health, Inc., 7101 College Blvd., Overland Park, KS 66210, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210:

NADA number	Drug name
006-623	Caparsolate
008-422	Seleen Suspension
010-092	Gallimycin-50P Premix
010-346	Combuthal Powder
012-123	Gallimycin-100, Gallimycin LA Injectable, Erythro-200 Injection
033-157	Spectam Scour Halt
035-157	Gallimycin Poultry Formula
035-455	Gallimycin-36/Dry
035-456	Gallimycin 36 Sterile
038-241	Erythro +ZOA+ARS Acid
038-242	Erythro +AMP+ETHO
038-624	Pro-Gallimycin-10
038-661	Spectam Water Soluble Concentrate
040-040	Spectam Injection
041-955	Erythromycin Premix
044-756	Butatron Tablets
045-416	Butatron Injection
048-287	Oxytetracycline-50 Injection

NADA number	Drug name
055-002	Chloramphenicol Injection
055-059	Viceton Tablets
065-275	Penicillin VK Filmtab
065-276	Veesyn Granules for Oral Solution
065-383	Procaine G Penicillin Mastitis Tubes
065-384	Procaine G Penicillin Mastitis Tubes
093-483	Spectam Injectable
093-515	Spectam Tablets
095-218	Dexamethasone Tablets
097-397	Syncro-Mate-B
098-379	Cystorelin Injectable
100-128	Medipak Tylan 10
101-690	Erythro-100 Injectable
102-656	Gallimycin Poultry Formula
107-506	Carbam Tablets & Film Coated Tablets
113-510	Equipalazone
118-032	Carbam Palatabs
118-979	Butatron Oral Gel
119-142	Injectable Iron 10%
120-615	Sustain III Calf & Cattle Bolus
123-815	Dexamethasone Sodium Phosphate Injection
124-241	Oxytocin Injection
126-504	Nitrozone Ointment
128-089	Dexamethasone Sterile Solution
134-930	Syncro-Mate-B
200-050	Neomycin 325 Soluble Powder
200-103	Penicillin G Potassium
200-147	Gentamicin Sulfate Injection

Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor. The drug labeler code assigned to Sanofi Animal Health, Inc., is being retained as the drug labeler code for Rhone Merieux, Inc.

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).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "Sanofi Animal Health, Inc." and by alphabetically adding a new entry for "Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210.....050604" and in the table in paragraph (c)(2) in the entry for "050604" by removing the sponsor name "Sanofi Animal Health, Inc." and adding in its place "Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210".

Dated: June 12, 1995.

George A. Mitchell,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1307, 1309, 1310, 1313 and 1316

[DEA No. 112F]

RIN 1117-AA23

Implementation of the Domestic Chemical Diversion Control Act of 1993 (PL 103-200)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule establishes regulations to implement the Domestic Chemical Diversion Control Act of 1993 (DCDCA or Act). These regulations provide additional safeguards to prevent and detect the diversion of listed chemicals by illicit drug manufacturers.

EFFECTIVE DATE: August 21, 1995. Persons seeking registration must apply on or before October 5, 1995 in order to continue their business pending final action by DEA on their application.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION: On October 13, 1994, DEA published a notice of proposed rulemaking (NPRM) entitled Implementation of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103-200) in the **Federal Register** (59 FR 51887). The NPRM proposed to amend Title 21, Code of

Federal Regulations (21 CFR) by adding a new Part 1309, relating to the registration of List I chemical manufacturers, distributors, retail distributors, importers and exporters; revising Parts 1310 and 1313 to amend the recordkeeping and reporting requirements for domestic as well as import/export activities; adding new procedures with respect to the exemption of regulated chemicals, including chemical mixtures and certain drug products that are marketed under the Food, Drug and Cosmetic Act; adding new procedures regarding "brokers", "traders" and "international transactions"; and revising Part 1316 with respect to DEA's administrative inspection authority.

There are two additional notices that DEA has published in the **Federal Register** that relate to these regulations. On March 24, 1994 an Interim Rule notice entitled Provisional Exemption From Registration for Certain List I Chemical Handlers was published in the **Federal Register** (59 FR 13881). This rule grants a temporary exemption from the registration requirements of the DCDCA. The exemption will remain in effect for any person who files with DEA a properly completed application for registration on or before October 5, 1995, until such a time as DEA takes final action on their application.

DEA published the second notice in the **Federal Register** on December 9, 1994, (59 FR 63738) withdrawing, for further study, Sections 1310.05(d) and 1310.06(h), which relate to manufacturer reports, and Sections 1310.12 and 1310.13, which relate to the exemption of chemical mixtures. The regulations regarding manufacturer reports and the exemption of chemical mixtures will be re-proposed at a later date following additional consultations with the affected chemical industry. Formal comments that were received in response to the NPRM regarding the withdrawn sections will be given consideration in the redrafting of a new proposal for these sections.

Regulatory Flexibility and Small Business Impact

As required under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.), DEA addressed in detail regulatory flexibility and small business impact as part of the NPRM. The NPRM discussed the difficulty in determining with certainty how many persons would continue to handle regulated ephedrine drug products, and thus be subject to the regulations. This is due to the rapidly changing market affected by state laws restricting the availability of ephedrine, the availability of alternative

products that are not regulated, and the intent of the DCDCA to eliminate sales to clandestine laboratories.

No comments were received on this topic or on DEA's estimate of the number of persons that will seek registration to handle regulated ephedrine drug products. Since publication of the NPRM, the number of states taking restrictive actions has increased. DEA is now aware of twelve states that have enacted laws controlling regulated ephedrine drug products, eleven by making them either prescription only or a controlled substance, and one by setting state licensure and reporting requirements. An additional four states have recently introduced legislation to control the products, three by making them a controlled substance and one by setting age restrictions and requiring reports of all transactions. In addition, DEA has documented that several wholesalers of regulated ephedrine drug products, the primary source of supply for retail distributors, have changed their product line to combination products that are not subject to regulation. Finally, recent reports that the Food and Drug Administration (FDA) is considering moving ephedrine into the prescription drug category may further influence persons handling ephedrine drug products. Under the circumstances, the number of retail distributor applicants under the DCDCA remains uncertain.

In the NPRM, DEA was able to provide relief from the chemical registration requirement for persons handling regulated ephedrine drug products who are already registered with DEA to engage in similar activities with controlled substances. In addition, manufacturers of List I chemicals for internal use, with no subsequent distribution or exportation of the chemical, were also exempted from the registration requirement. Both of these proposals have been retained in the final rule. Consideration was also given to exempting retail distributors from the registration, recordkeeping and reporting requirements. However, such an action would negate the purpose of the DCDCA by leaving a significant portion of the sales of regulated ephedrine drug products unregulated.

Following submission and review of the comments concerning the proposed regulations, two requirements were identified which DEA determined could be removed from the final regulations to reduce the impact of compliance without compromising the control goals of the DCDCA. The proposals were the reporting requirement for sales of 375 dosage units or more of regulated ephedrine drug products (proposed