§ 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 of 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