more than 50 percent of the milk which is marketed within the Middle Atlantic marketing area to sign a proposed marketing agreement tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of this order amending the order is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the order as hereby amended; and

(3) The issuance of the order amending the order is favored by at least two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the Middle Atlantic marketing area.

List of Subjects in 7 CFR Part 1004

Milk marketing orders.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, the handling of milk in the Middle Atlantic marketing area shall be in conformity to and in compliance with the terms and conditions of the order, as amended, and as hereby further amended, as follows:

1. The authority citation for 7 CFR Part 1004 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 1004—MILK IN THE MIDDLE ATLANTIC MARKETING AREA

2. Section 1004.7 is amended by revising paragraphs (a)(1) and (a)(4); revising paragraph (d)(1) and by adding a new paragraph (g) to read as follows:

§ 1004.7 Pool Plant.

* * * * *

(a) * * *

(1) Milk received at such plant directly from dairy farmers (excluding milk diverted as producer milk pursuant to § 1004.12, by either the plant operator or by a cooperative association, and also excluding the milk of dairy farmers for other markets) and from a cooperative in its capacity as a handler pursuant to § 1004.9(c); or

* * * * *

(4) A plant's status as an other order plant pursuant to paragraph (f) of this section will become effective beginning the third consecutive month in which a plant is subject to the classification and pricing provisions of another order.

* * * * *

(d) * * *

(1) A reserve processing plant operated by a cooperative association at which milk from dairy farmers is received if the total of fluid milk products (except filled milk) transferred from such cooperative association plant(s) to, and the milk of member producers physically received at, pool plants pursuant to § 1004.7(a) is not less than 25 percent of the total milk of member producers during the month.

* * * * *

(g) The applicable shipping percentage of paragraphs (a) and (b) or (d) of this section may be increased or decreased by the market administrator if the market administrator finds that such revision is necessary to encourage needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for revision either on the market administrator's own initiative or at the request of interested parties. If the investigation shows that a revision of the shipping percentages might be appropriate, the market administrator shall issue a notice stating that the revision is being considered and invite data, views and arguments. Any request for revision of shipping percentages shall be filed with the market administrator no later than the 15th day of the month prior to the month for which the requested revision is desired effective.

3. Section 1004.12 is amended by revising paragraphs (d)(2)(i) and (d)(2)(ii) and by adding a new paragraph (g) to read as follows:

§ 1004.12 Producer.

* * * * *

(d) * * *

(2) * * *

(i) All of the diversions of milk of members of a cooperative association or a federation of cooperative associations to nonpool plants are for the account of such cooperative association or federation, and the amount of member milk so diverted does not exceed 55 percent of the volume of milk of all members of such cooperative association or federation delivered to or diverted from pool plants during the month.

(ii) All of the diversions of milk of dairy farmers who are not members of a cooperative association diverting milk for its own account during the month are diversions by a handler in his capacity as the operator of a pool plant from which the quantity of such nonmember milk so diverted does not exceed 45 percent of the total of such nonmember milk for which the pool plant operator is the handler during the month.

* * * * *

(g) The applicable percentages in paragraphs (d)(2)(i) and (d)(2)(ii) of this section may be increased or decreased by the market administrator if the market administrator finds that such revision is necessary to encourage needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for revision either on the market administrator's own initiative or at the request of interested parties. If the investigation shows that a revision of the diversion limit percentages might be appropriate, the market administrator shall issue a notice stating that the revision is being considered and invite data, views and arguments. Any request for revision of the diversion limit percentages shall be filed with the market administrator no later than the 15th day of the month prior to the month for which the requested revision is desired effective.

Dated: October 25, 1995.

Shirley R. Watkins,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 95–26918 Filed 10–30–95; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[DEA No. 131N]

Clarification of Coincident Activities for Researchers

AGENCY: Drug Enforcement Administration, DOJ.

ACTION: Policy Statement.

SUMMARY: The Drug Enforcement Administration (DEA) is issuing a policy statement to clarify policy regarding the manufacturing of controlled substances under a researcher registration. DEA regulations allow a person registered with DEA or authorized to conduct research with controlled substances listed in Schedules II through V to manufacture such substances if and to the extent that the manufacture of such substances is set forth in a statement filed with the application for registration. In addition, a registered researcher may distribute a substance specifically manufactured for research purposes to such other persons who are registered or authorized to conduct chemical analysis, instructional activities or research with that substance. This document clarifies the types of manufacturing activities that may not be carried out as a coincident activity under a researcher registration.

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: The Controlled Substances Act of 1970 (CSA) sets forth a system to control and prevent the diversion of controlled substances. Title 21, Code of Federal Regulations (21 CFR), Parts 1300 to End contains the specific regulatory requirements to implement the CSA, including the registration, recordkeeping, security, reporting and quota provisions. Title 21 CFR 1301.22(a) describes the eleven activities that require registration with DEA. Under this section, manufacturing and research are designated as independent activities for which separate registrations are required. However, 21 CFR 1301.22(b) describes specific coincident activities for which separate registrations are not required. Specifically, 21 CFR 1301.22(b)(5) states that a person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized, among other things, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances.

The present DEA policy permits the manufacture of small amounts of bulk material under a researcher registration if: (1) the quantities are set forth in, and consistent with, the statement filed with the application for registration,; and (2) if the purpose, as set forth in the statement filed with the application, is to develop synthesis procedures or other research not related to dosage form development.

This policy is necessary to preserve the closed system of distribution, as well as protect the integrity of the attendant quota, security, recordkeeping and reporting requirements of the system. DEA is obligated to enforce the distinctions among those independent activities set forth in 21 CFR 1301.22(a). Manufacturers are held to more stringent requirements than researchers because of the greater threat of diversion associated with manufacturing.

It has come to the attention of DEA that certain registrants are manufacturing bulk material under a researcher registration for the purpose of: (1) performing dosage form development (to include associated regulatory requirements such as production of batches as mandated by the Food and Drug Administration (FDA); or (2) distributing such material to other research registrants for furtherance of dosage form development and associated requirements. In addition, several dosage form manufacturers have procured large quantities of Schedule II controlled substances under researcher registrations for use in product development. Activities of this type are not consistent with the mandate of the CSA to maintain a closed regulatory system to prevent diversion. In order to ensure that all registrants understand the meaning and requirements of 21 CFR 1301.22 and to ensure adequate safeguards against diversion, DEA is issuing this clarification of the permissible scope of manufacturing under a researcher registration.

For the purposes of 21 CFR part 1301, the following dosage form development activities are not considered research and must be conducted under a manufacturer registration: (a) activities for the purpose of satisfying regulatory requirements such as FDA submissions or good manufacturing practice; (b) activities associated with establishing the manufacturing processes and procedures, including, but not limited to, production of material used for pilot, scale-up and reformulation studies, as well as the studies themselves; and (c) all activities associated with such development including, but not be limited to, bioavailability, formulation, stability, an validation studies. While these activities may be considered research under FDA requirements, 21 CFR part 1301 must be read within the context of the CSA and its attendant requirements concerning quotas, recordkeeping, security and reporting. DEA does not consider such dosage form development to be a coincident research activity as contemplated by 21 CFR 1301.22(b); the production of material for such activities is manufacturing. The exemption for separate registrations for certain coincident activities is intended to facilitate research by allowing for the limited manufacture of controlled substances for those activities related directly to the research set forth in the statement filed with application for researcher registration. However, once the manufacture of controlled substances for research moves beyond the scope of the research and becomes product development, as described above, those manufacturing activities are not longer considered to be coincident activities. Any person seeking to manufacture controlled substances for such purposes must meet the primary requirements for registration as a manufacturer as set forth in 21 U.S.C. 823.

Requiring registration as a manufacturer for product development activities will present no additional obstacles, due to DEA's Final Rule, published on June 20, 1995 (60 FR 32099, Registration of Manufacturers and Importers of Controlled Substances), to amend the regulations to eliminate the requirement of an administrative hearing on objections, raised by third-party manufacturers, to the registration of certain bulk manufacturers of controlled substances. As noted in the Final Rule, DEA is aware that some manufacturers have attempted to use the hearing process to obstruct or delay action on new applications for registration as a bulk manufacturer. This may have contributed to the practice of conducting product development activities under researcher registrations to avoid such delays. The amendment of the hearing requirements removes any such justification for resorting to such practices.

DEA cannot predict when an individual's activities may shift from a researcher to a manufacturer. Therefore, it is imperative that a person who is conducting research, whose activities move from bench type to scale up and development, be aware and alert to the requirements of 21 CFR 1301.22. For any questions or guidance in this area, DEA should be contacted for a specific clarification.

Dated: October 24, 1995.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 95–26948 Filed 10–30–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8611]

RIN 1545–AS40

Conduit Arrangement Regulations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD