

§ 630.81 Clinical trials to qualify for license.

In addition to demonstrating that the measles component meets the requirements of § 630.31, the measles and smallpox antigenicity of the final product shall be determined by clinical trials of adequate statistical design conducted with three consecutive lots of final vaccine manufactured by the same methods and administered as recommended by the manufacturer. A major skin reaction to the smallpox component of the vaccine shall result in at least 95 percent of smallpox susceptible recipients, and a protective antibody response demonstrating the immunogenic effect of measles shall result in at least 90 percent of the measles susceptible recipients. Based upon data submitted by each manufacturer requesting licensure and comparative testing by the Food and Drug Administration, the Commissioner will establish the type of test and the requisite antibody levels indicating seroconversion which must be met by the manufacturer. There also shall be a demonstration of safety of the product, when administered as recommended by the manufacturer, under circumstances wherein adequate clinical and epidemiologic surveillance of illness has been maintained.

2. By revising § 630.83 to read as follows:

§ 630.83 Reference preparations.

Reference Measles Virus and Reference Smallpox Vaccine and reconstitution fluid shall be obtained from the Bureau of Biologics. The Reference Measles Virus shall be used as a control for correlation of virus titers for the measles component of the product. The Reference Smallpox Vaccine shall be used to determine the potency of the smallpox component of the product.

3. By revising § 630.84(b) to read as follows:

§ 630.84 Potency tests.

(b) *Smallpox.* Each lot of the product shall be tested for potency as prescribed in § 630.73. The product is satisfactory if the vaccinia virus contained in one human dose is at least equivalent to that contained in 0.3 milliliter of the Reference Smallpox Vaccine diluted 1:100.

4. By revising § 630.86 (d) and (e) (2), deleting (e) (4), and revising (e) (5) and redesignating it as (e) (4) as follows:

§ 630.86 General requirements.

(d) *Labeling.* In addition to the items required by other applicable labeling provisions of this chapter, labeling shall contain a statement that the product is intended for primary immunization only, for administration only by jet injector, and a description of the method of administration.

(e) * * *

(2) A total of no less than two 25-milliliter volumes, in a frozen state

(-60° C), of the bulk measles component prior to clarification and containing no preservative or adjuvant, and no less than one 10-milliliter volume in a frozen state (-60° C), of the bulk measles component after clarification and containing stabilizer but no preservative or adjuvant, taken prior to filling into the final containers.

(3) * * *

(4) A sample consisting of no less than sixteen 10-dose vials, or twelve 25-dose vials, or ten 50-dose vials of vaccine in final labeled containers plus sufficient diluent in final labeled containers to reconstitute the vaccine.

(5) [Deleted].

Effective date. This order shall be effective February 14, 1975.

(Sec. 351, 58 Stat. 702 (42 U.S.C. 262))

Dated: February 10, 1975.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.75-4162 Filed 2-13-75;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Concentrate of Poppy Straw, Addition to Schedule II and Authorizing Its Importation

A notice was published in the FEDERAL REGISTER on Friday, December 20, 1974 (39 FR 44033-4), authorizing the importation of concentrate of poppy straw and proposing amendments to Title 21 of the Code of Federal Regulations which place this substance in Schedule II and require reporting of such importation by manufacturers. All interested persons were given until January 22, 1975, to submit their comments and objections.

The single comment received, that of the Bell Pharmacal Corp., did not object to the proposed rulemaking. Therefore, based upon consideration of the factors set forth in 39 FR 44033-4, the Administrator of the Drug Enforcement Administration, under authority vested in the Attorney General by sections 201(d), 301, and 1002 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(d), 821, and 952, respectively) and delegated to the Administrator by § 0.100 of Title 28 of the Code of Federal Regulations, hereby orders that Parts 1304 and 1308 of Title 21 of the Code of Federal Regulations be amended as follows:

1. A new § 1304.42 is added as follows:

§ 1304.42 Reports from manufacturers importing concentrate of poppy straw.

(a) Every manufacturer importing concentrate of poppy straw shall submit in addition to Form 333, Form DEA 247 (c) accounting for the importation and

for all manufacturing operations performed between importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in the returns on DEA Form 333 (§ 1304.38) and its supplements. DEA Form 247(c) shall be submitted quarterly to the Regulatory Investigations Section, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from concentrate of poppy straw shall consist of summaries with supporting detail sheets accounting for original manufacture from concentrate of poppy straw, production from morphine for further manufacture, and also accounting for stocks of concentrate of poppy straw, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (DEA 247(c)) supporting the summary of original manufacture from concentrate of poppy straw shall show separately the amount of concentrated poppy straw imported, the concentrated poppy straw used for the extraction of alkaloids, subsequent manufacture from those alkaloids, and the inventory of concentrated poppy straw at the close of the reporting period.

(d) Upon importation of concentrate of poppy straw, samples will be selected and assays made by the importing manufacturer in a manner and according to a method previously approved by DEA. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Upon withdrawal of concentrate of poppy straw from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the concentrate of poppy straw will be associated with the lot assay and identified in reports.

(f) Where factory procedure is such that partial withdrawals of concentrate of poppy straw are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) Concentrate of poppy straw derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than

mere packaging has been completed. Products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and there are ready either for use in further manufacture or for packaging for distribution.

(h) Subject to §1303.24(c) of this chapter, no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(i) In making conversions of concentrate of poppy straw alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

2. Section 1308.12 is amended by adding a new (b) (5) as follows:

§ 1308.12 Schedule II.

(b) * * *

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy), 9670.

This order is effective February 14, 1975.

Dated: February 11, 1975.

JOHN R. BARTELS, Jr.,
Administrator,

Drug Enforcement Administration.

[FR Doc.75-4235 Filed 2-13-75; 8:45 am]

Title 34—Government Management
CHAPTER II—OFFICE OF FEDERAL MANAGEMENT POLICY, GENERAL SERVICES ADMINISTRATION

SUBCHAPTER D—PROPERTY MANAGEMENT
[FMC 75-1]

PART 234—ENSURING CONSIDERATION OF USERS' EXPERIENCE WITH FEDERAL AGENCY SUPPLY SUPPORT SYSTEMS

Policies and Procedures

This document is issued pursuant to Executive Order 11717 dated May 9, 1973, subject: Transferring Certain Functions from the Office of Management and Budget to the General Services Administration and the Department of Com-

merce; and under authority vested in the Administrator of General Services by the Federal Property and Administrative Services Act of 1949, as amended.

FMC 75-1, dated February 7, 1975; provides policies and procedures to ensure that supply support systems provide a positive means for the communication and consideration of users' experience.

Effective date. This regulation is effective February 7, 1975.

Dated: February 7, 1975.

DWIGHT A. INK,
Acting Administrator of
General Services.

Part 234 of 34 CFR is added to read as follows:

Sec.	
234.1	Purpose.
234.2	Background.
234.3	Policy intent.
234.4	Applicability and scope.
234.5	Policies and procedures.
234.6	Responsibility.
234.7	Reporting requirement.
234.8	Inquiries.

AUTHORITY: The adoption by the executive branch of Recommendation D-2 of The Commission on Government Procurement report to Congress dated December 31, 1972.

§ 234.1 Purpose.

This part establishes policies and procedures to ensure that supply support systems provide a positive means for the communication and consideration of users' experience.

§ 234.2 Background.

(a) The Commission on Government Procurement in its report to the Congress dated December 31, 1972, provides in Chapter 3, Part D, compelling examples of the need to consider users' satisfaction with their supply support systems. Because of its findings, the Commission issued Recommendation D-2 calling for the executive branch to "Provide a positive means for users to communicate satisfaction with their (supply) support system as a method of evaluating its effectiveness and ensuring user confidence."

(b) Under the procedures established by the executive branch for dealing with the recommendations of the Commission, an interagency task group was assigned to consider the merits of Recommendation D-2. The task group found that executive agencies are aware of the need to consider user satisfaction in the operation of centralized supply systems. This awareness is evidenced by techniques currently in use to discover and deal with users' complaints. However, the task group concluded that a higher priority should be given to the practice of communication with user activities as a tool for evaluating the performance of supply support systems. The decision to adopt the Commission's recommendation is based on the task group's findings.

§ 234.3 Policy intent.

This part is intended to ensure that the supply support systems of all Federal agencies provide a positive means for communication with users and consideration of their experience with those systems.

§ 234.4 Applicability and scope.

The provisions of this part apply to all supply support systems of executive departments and establishments with regard to intra-agency supply support systems and to the interagency supply support systems managed by the Department of Defense, the General Services Administration, and the Veterans Administration.

§ 234.5 Policies and procedures.

(a) It is the policy of the executive branch that needed goods and services be acquired and provided to the user in an economic, efficient, and effective manner.

(b) Government acquisition systems must consider such factors as agency resources, statutory sources, and social and economic programs while meeting end product users' needs. An end product user's satisfaction is directly related to the action taken on his ideas and problems by those on whom he must depend for support.

(c) Each agency operating one or more supply support systems shall establish procedures to provide for periodic reviews of existing methods of expressing end product user's satisfaction with the support system(s). In evaluating the effectiveness of the support system, the procedures shall provide for (1) evaluating the effectiveness of those methods; (2) determining whether end product user's satisfaction is a factor in evaluating the performance of the support system; and (3) taking actions to ensure that procedures provide a positive means of obtaining and considering the end product user's satisfaction. If improvements are warranted, consideration shall be given to establishing supply liaison programs using publications to assist the users, coordinating proposed procedures with the end product users before they are implemented, and conducting meetings and seminars with users to obtain direct information regarding the supply system.

§ 234.6 Responsibility.

Heads of executive departments and agencies are responsible for implementing this part.

§ 234.7 Reporting requirement.

Within 180 calendar days each agency shall inform the Office of Federal Management Policy (AMP), GSA, of the steps taken to implement the provisions of this part.

§ 234.8 Inquiries.

Further information concerning this part may be obtained by contacting:

General Services Administration (AMP),
Washington, D.C. 20405.
Telephone: IDS 183-7528, FTS 202-343-7528

[FR Doc.75-4196 Filed 2-13-75; 8:45 am]