

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1318]

Draft Guidance for Industry on Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment." This draft document is intended to provide guidance on the development of drug and biological products intended to treat venous stasis ulcers, diabetic foot ulcers, pressure ulcers, and burn wounds. The draft guidance contains recommendations about labeling claims, outcome measures, trial design, and special considerations for preclinical development.

DATES: Submit written comments on the draft guidance by August 28, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For information on how to obtain copies, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Maryjane Walling, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301-827-2268;

Bette A. Goldman, Center for Biologics Evaluation and Research (HFM-500), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5098; or

Charles N. Durfor, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment." This draft document is intended to provide guidance on the

development of drug and biological products intended to treat venous stasis ulcers, diabetic foot ulcers, pressure ulcers, and burn wounds. The draft guidance contains recommendations about labeling claims, outcome measures, trial design, and special considerations for preclinical development.

Extensive discussions were held during two advisory committee meetings in July and November 1997 about the treatment of ulcers and burns. In response to requests from industry, the agency has developed this draft guidance. The comments received from industry, professional societies, and consumer groups represented at those meetings have been taken into consideration in drafting this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on clinical development of products for the treatment of chronic cutaneous ulcer and burn wounds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. How to Obtain Copies

You may submit written requests for single copies of the draft guidance by sending one self-addressed adhesive label to assist the office in processing your request to:

The Office of Training and Communications,
Division of Communications Management,
Drug Information Branch (HFD-210),
Center for Drug Evaluation and Research,
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857;

Or

The Office of Communication, Training and Manufacturers Assistance (HFM-40),

Center for Biologics Evaluation and Research,
Food and Drug Administration,
1401 Rockville Pike,
Rockville, MD 20852-1448,
CBER Voice Information System: 1-800-835-4709 or 301-827-1800
Fax: 1-888-CBER-FAX or 301-827-3844;

Or

The Division of Small Manufacturers Assistance (HFZ-220),
Center for Devices and Radiological Health,
Food and Drug Administration,
1350 Piccard Dr.,
Rockville, MD 20850,
Phone: 800-638-2041,
E-mail: DSMA@CDRH.FDA.GOV,
Fax: 1-301-443-8818,
Facts-On-Demand: 800-899-0381.

An electronic version of the draft guidance also is available via the Internet at CDER's Internet site at <http://www.fda.gov/cder/guidance/index.htm> or at CBER's Internet site at <http://www.fda.gov/cber/guidelines.htm>.

Dated: June 16, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1296]

Final Guidance: Importation of Pasteurized Milk Ordinance (PMO) Defined Dairy Products (M-I-00-4); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Importation of PMO Defined Dairy Products (M-I-00-4)". This guidance provides information that States can use to respond to inquiries regarding the importation of "Grade A" dairy products from other countries.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Persons who wish to submit electronic comments should go to FDA's home page at www.fda.gov, select "Dockets," and follow the instructions. Submit written requests for single copies of the guidance entitled "Importation of PMO Defined Dairy Products (M-I-00-4)" to Charlotte Epps, Milk Safety Branch (HFS-625), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your requests. See section III of this document for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Smucker, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-8178, e-mail: jsmucker@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is the Federal agency with responsibility under the Federal Food, Drug, and Cosmetic Act for the safety of the United States' dairy products. In the case of those dairy products regulated by the States under the Grade "A" milk safety program, one way FDA has chosen to fulfill this charge is by providing technical assistance to State regulators under the authority of various sections of the U.S. Public Health Service Act.

The National Conference on Interstate Milk Shipments (NCIMS) is a voluntary coalition of regulators from U.S. States and one U.S. commonwealth. These regulators have banded together in this organization to ensure the safety of Grade "A" milk and milk products shipped in interstate commerce and to minimize duplicate regulatory restrictions on these products if they are produced according to this group's stringent public health standards.

As the need arises, FDA provides information to the States in the NCIMS and others interested in production and processing of Grade "A" milk and milk products.

Under the procedures of the NCIMS, administrative and other miscellaneous information is transmitted to FDA regional staff and through them to State agencies in the form of a memorandum of information (M-I). Several M-I's are issued each year; M-I-00-4 is this type of memorandum. It is being provided to transmit an FDA opinion. This opinion clarifies that the food protective measures provided under the NCIMS system are an important part of the U.S.'s appropriate level of protection for Grade "A" dairy products. This guidance also describes three options that both FDA and the NCIMS have accepted to ensure that the public

health effect of these food protective measures is not circumvented when these dairy products are imported.

This level 2 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This guidance document represents the agency's current thinking on the subject and it does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation or both.

What follows is a verbatim copy of this memorandum.

"M-I-00-4"

April 11, 2000

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Milk Safety Branch (HFS-626)

Subject: Importation of PMO Defined Dairy Products

This memorandum provides guidance that States can use to respond to inquiries regarding the importation of "Grade A" dairy products from other countries. This guidance document represents the agency's current thinking on this subject and it does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation or both.

I. Background Information

International trade agreements to which the United States is signatory allow countries to establish measures to ensure safety of food within their countries. The measures, however, must be applied in a manner so that they do not arbitrarily discriminate between products from different countries or treat domestic products more favorably than imported products without justification.

The World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) also obligates the over 160 member countries to consider the "equivalence" of another country's food protection measures if an exporting country requests such consideration. The determination of equivalence is made by the importing country based on whether the exporting country's measures meet the level of protection deemed appropriate by the importing country, as provided by its own measures. Because the WTO agreements only went into effect in 1995, the concept of equivalence is only now beginning to be utilized in international trade. Nevertheless, Article 4. Equivalence of the SPS Agreement exists as an obligation for all WTO Member governments.

The system of controls used to provide the U.S.'s appropriate level of protection for "Grade A" dairy products is described in the current edition of the "Grade A Pasteurized Milk Ordinance" (PMO) and related documents. Since the early 1950's, States and FDA using a system of ratings and check

ratings have verified the level of protection provided by the PMO in domestic (interstate) commerce. The requirements for these ratings and check ratings are specified in the current edition of the "Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments" (Procedures).

In a 1977 Memorandum of Understanding (MOU) with the National Conference on Interstate Milk Shipments (NCIMS), FDA accepted the standards, requirements and procedures of the NCIMS to manage the public health risks associated with "Grade A" milk and milk products. FDA considers this NCIMS milk safety program to be adequate for the protection of the health and safety of the consumer.

Current Status

FDA and the NCIMS have identified and mutually accepted three options which are consistent with NCIMS "Procedures" and which will allow States to receive PMO defined "Grade A" products produced outside of the United States.

These options are:

1. A dairy firm outside of the United States could contract with any current NCIMS member's regulatory/rating agency to provide the "Grade A" milk safety program in total. This would include the regulatory licensing, dairy farm and milk plant inspection and sampling, pasteurization equipment testing, laboratory certification and rating/NCIMS listing certification. To use this option the firm would be required to abide by all applicable NCIMS regulatory and rating requirements and the regulatory/rating agency would have to agree to treat the firm as if it were located within its jurisdiction for all purposes, including inspection and enforcement. Ratings of the firm would be check-rated by FDA.

2. The importing country, or a political subdivision thereof, may become a full member of the NCIMS subject to all NCIMS rules and enjoying all privileges of a U.S. State. This would require, among other things, that the milk regulatory agency(ies) of the importing countries adopt and enforce rules and regulations which are the same as those required in the United States and abide by all applicable NCIMS regulatory and rating requirements. Their ratings would be check-rated by FDA in the same way as State ratings. FDA would certify their rating, sampling surveillance and laboratory evaluation officers.

3. FDA can evaluate the importing country's system of assuring the safety of dairy products and compare the effect of that system with the effect of the United States system on the safety of dairy products produced domestically. The NCIMS has adopted a procedure to accept FDA findings of equivalence and to allow NCIMS member States to accept products produced within the scope of such a finding.

Emerging International Issue

As trade barriers are removed and trade between countries increases, there are more frequent requests to allow the importation of "Grade A" defined products that originate in

other countries. The most common concern is how an adequate level of safety can be verified.

Under current Federal law and regulation, FDA can only take action on imported food products based on a violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). Importation of milk products without adhering to any of the three options described above, is NOT, in and of itself, a violation of the FFDCA.¹

Based on the 1977 MOU, milk protection measures in the United States have been set by the combined efforts of FDA and the States under the NCIMS milk safety program.

Under this program the States must adopt as law and enforce the provisions of the PMO as specified in the "Procedures". Their collective actions are intended to insure that milk marketed in the United States meets the U.S. appropriate level of protection.

FDA works with the States to verify that the U.S. level of protection is met under authority of the Public Health Service Act (42 U.S.C.). Under this act FDA has a broad mandate to assist States technically and to evaluate their performance under the "Procedures". However, current regulations promulgated under this act do not provide an adequate base for direct FDA enforcement of the PMO.

If the U.S. level of protection, as currently met by consistent State enforcement of the PMO, is to continue to be met, it must be accomplished by States continuing to collectively require this level of protection.

Under U.S. trade agreements products imported from another country must be treated by States and by FDA, no less favorably than those products imported from another State.

The three options in this memorandum can be used by States to assure that the same level of safety for "Grade A" defined products is achieved for products produced in other countries.

In order for the agency to function within the provisions of the MOU and fulfill its food safety responsibility, FDA will note, in State program evaluations, if a State is not requiring the NCIMS "Grade A" level of protection in interstate or international commerce.

If after a reasonable opportunity to correct this situation, a State still does not provide their citizens with this level of protection, FDA may declare that the State is not in substantial compliance under the "Procedures * * *"

Copies of this memorandum are enclosed for your distribution to District Milk Specialists, State milk regulatory agencies, State Laboratory Evaluation Officers and State Milk Rating Officers in your region. This memorandum is also available on the FDA Prime Connection Computer bulletin board system (Internet address: <http://www.cfsan.fda.gov>), and should be widely distributed to representatives of the dairy industry and other interested parties. /S/

II. Comments

Interested persons may submit to the Dockets Management Branch (address

above) written or electronic comments on the guidance entitled "Importation of PMO Defined Dairy Products (M-I-00-4)" at any time. Two copies of written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and written and electronic comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies of the guidance entitled "Importation of PMO Defined Dairy Products (M-I-00-4)" at <http://www.cfsan.fda.gov>.

Dated: June 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

or other forms of information technology.

Proposed Project: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915-0219)—Revision

State AIDS Drug Assistance Programs (ADAPs), funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996 [Pub. L. 104-146], are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV positive or diagnosed with AIDS. Due to the increasing demand, the Division of Service Systems (DSS), Health Resources and Services Administration (HRSA) recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposes to revise the current data collection form to better collect relevant client utilization data and program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to monitor nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain services for clients throughout the fiscal year. The revised form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs, and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff, and policymakers at both the Federal and State level to better understand the level of client demand for medications and the resources needed to meet those needs.

The revised report will collect time-specific data for the number of enrolled clients, the number of new clients, the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as a projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV

¹ Milk or cream may also need a permit under the provisions of the Federal Import Milk Act.