

manufactured lot is acceptable for release.

Accordingly, as provided under § 610.2, the Director of CBER is no longer requiring that manufacturers of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products submit samples and protocols to CBER. FDA will continue to monitor companies' compliance with the requirement in § 610.1 (21 CFR 610.1) that they assay each lot and release only those lots that meet release specifications.

FDA intends to revise the guidance entitled, "Guidance on Alternatives to Lot Release for Licensed Biological Products," (58 FR 38771, July 20, 1993) to reflect the new procedures. Manufacturers who do not receive a letter, but think that one of their licensed products meets the interim definition, may contact Jerome A. Donlon (address above).

Eliminating FDA lot-by-lot release should not compromise the safety, purity, or potency of licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. Because of process validation and current in-process controls and testing for these products, identity, purity, and potency can be controlled and measured. In addition, the in-process and end-product release specifications can be validated for these products. Therefore, submission of lot release samples and protocols are no longer viewed by FDA as essential to the ongoing assurance of safety for these products.

Eliminating lot-by-lot release for these products furthers FDA's harmonization of its regulation of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products between CBER and the Center for Drug Evaluation and Research.

Manufacturers are still required under § 610.1 to test each lot and release only those that meet release specifications. During inspections, FDA will monitor compliance with those requirements. Manufacturers continue to be required to maintain adequate records and retention samples under 21 CFR 211.170 and 211.180.

Interim Definition

FDA has prepared the following interim definition for a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product:

A chemical entity(ies) whose identity, purity, impurities, potency, and quantity can be determined and controlled.

Identity:

a. *Recombinant DNA Biotechnology Products*

The primary structure is known (i.e., amino acid sequence), and

The secondary structure is known (e.g., disulfide linkage), and

Post-translational modifications are known (e.g., glycosylation), or

b. *Monoclonal Antibodies*

The identity can be determined by rigorous physicochemical and immunochemical characterization without fully knowing its chemical structure.

Purity and impurities:

The purity is quantifiable.

The impurities are quantifiable, and identified if feasible.

Potency and quantity:

The biological activity is measurable.

The quantity is measurable.

Well-characterized therapeutic recombinant DNA-derived or monoclonal antibody biotechnology products require proper raw material controls, process validation and controls, and sensitive and validated test methods and specifications. FDA intends to use the definition to determine which products may be exempted from lot-by-lot release and to help determine which products may be eligible for other regulatory initiatives directed at well-characterized biotechnology products.

FDA invites comments on its proposed definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. In particular, FDA invites comments on whether the proposed definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products should be expanded to include other categories of products that would be considered to be well-characterized and should be categorically exempted from lot-by-lot release.

In the Federal Register of October 25, 1995 (60 FR 54695), FDA announced that it is sponsoring a public scientific workshop on December 11 through 13, 1995. At the workshop participants will be asked to refine the definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product as set forth above. After considering the information presented at the workshop, FDA may modify the interim definition given above. Manufacturers of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products affected by this change in policy will be notified by letter.

CBER does not intend for this notice to be comprehensive. If a manufacturer has questions concerning application of this policy to one of its licensed

products or the interim definition, it can discuss the matter with CBER. Although the interim definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products in this notice is not binding on either FDA or manufacturers of biological products and does not create or confer any rights for or on any person, it does represent the agency's current thinking on that definition.

Dated: December 4, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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[Docket No. 93N-371W]

Prescription Drug Product Labeling; Public Patient Education Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. The purpose of this workshop is to obtain views and opinions concerning the criteria for useful patient information, and is part of FDA's ongoing initiative to improve the distribution of adequate and useful prescription drug information to patients. FDA encourages health professionals, consumer groups, industry, academicians, other experts in the field, and interested parties to participate in the workshop. FDA also invites the designers of primary information systems, which produce either written information or computer programs that generate prescription drug patient information, to display their systems for educational purposes.

DATES: The public patient education workshop will be held on January 9 and 10, 1996, from 8:30 a.m. to 5 p.m. Submit registration notices for participants by December 26, 1995. Submit registration notices for designers of information systems by December 19, 1995. Submit written comments by January 31, 1996.

ADDRESSES: The public patient education workshop will be held at the National Institutes of Health, Natcher Auditorium, 9000 Rockville Pike, Rockville, MD. Pre-registration for workshop participants is encouraged, although not required, in order to facilitate logistical planning of the

breakout discussion groups. There is no registration fee for this workshop. Registration forms can be obtained by calling 301-443-5470 or writing to the Office of Health Affairs, ATTN: Patient Education Workshop, Food and Drug Administration (HFY-40), 5600 Fishers Lane, Rockville, MD 20857. Submit written views or comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The designers of information systems should call the contact person (address below) for registration information. A more detailed agenda and written presentations will be placed in the docket, identified with the docket number found in brackets in the heading of this document, at the Dockets Management Branch, and will be available for review between 9 a.m. and 4 p.m., Monday through Friday. A transcript of the general sessions of the workshop will be available for review or purchase (10 cents per page) at the Dockets Management Branch approximately 5 business days after the meeting. The breakout sessions will not be transcribed.

FOR FURTHER INFORMATION CONTACT: Thomas J. McGinnis, Office of Health Affairs (HFY-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5470.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 24, 1995 (60 FR 44182), FDA published a proposed rule which, if finalized, is intended to increase the dissemination of useful written prescription drug information to patients who receive prescription drugs on an outpatient basis. The agency believes that such information must be widely distributed and be of sufficient quality to promote the proper use of prescription drugs. The agency proposed goals (performance standards) that would define acceptable levels of information distribution and quality. To meet the performance standard for distribution of patient information, the agency proposed that by the year 2000, at least 75 percent of people receiving new prescriptions receive useful written information. This goal was adapted from the Public Health Service's "Healthy People 2000" report. In addition, the agency proposed that by the year 2006, at least 95 percent of the people who receive new prescriptions receive useful written information.

FDA proposed to periodically evaluate and report on the achievement of the goals. If the goals are not met in the specified timeframes, FDA proposed to either: (1) Implement a mandatory

comprehensive medication guide program, or (2) seek public comment on whether the comprehensive program should be implemented, or whether, and what, other steps should be taken to meet the patient information goals.

In the Federal Register of August 24, 1995, the agency proposed the following seven specific components for determining whether patient information is useful: Scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility. The agency defined these components of usefulness, as well as criteria that could be used to judge these components, and invited comments on their appropriateness. The agency also stated that it would hold a public meeting for interested parties to provide recommendations and rationale for evaluating usefulness of written information.

The agency will hold a public patient education workshop to discuss the methods and criteria for developing and evaluating the usefulness of written information. The patient education workshop will be designed to obtain recommendations from the public about the criteria that should be applied to help ensure that written information provided to patients is "useful."

The patient education workshop will be comprised of both formal presentations and open breakout discussion periods. Any interested person may attend and participate in the discussions. The workshop will include general sessions with presentations from FDA, health professional groups, consumer groups, the pharmaceutical industry, academicians, and parties with legal and regulatory expertise. The agency also intends to hold breakout sessions throughout the 2-day workshop to obtain broad participation and input from workshop attendees.

FDA believes that it would be helpful for workshop participants (including FDA staff) to learn about the design of current patient information systems, in particular, programs that generate drug-specific patient information. The agency invites the designers of primary information systems (not the customizers of systems for retail outlets) to display their systems at the workshop for educational purposes only. No sales or solicitations may be made by exhibitors at the workshop site. Due to space limitations, FDA may be forced to limit the number of systems on display. In doing so, FDA would seek to permit display of the most representative/comprehensive systems available for patient information. However, the

agency invites all interested persons to submit their views, comments, and descriptions of computer programs to the Dockets Management Branch (address above).

The agency notes that the comment period for the proposed rule that published in the Federal Register of August 24, 1995, has recently been extended until December 22, 1995 (60 FR 58025, November 24, 1995). Because this workshop will occur after the comment period has closed, the agency will accept additional comments to the proposed rule on the specific issues raised at the workshop. These comments will be considered as part of the agency's deliberations regarding further action on this rulemaking. For this limited purpose, written comments may be submitted to the Dockets Management Branch (address above) until January 31, 1996. Comments are to be identified with the docket number found in brackets in the heading of this document.

A summary of the workshop will be included in a subsequent Federal Register notice related to this prescription drug labeling initiative.

Dated: December 1, 1995.

William K. Hubbard,

Associate Commissioner for Policy.

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National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: December 11, 1995.

Time: 11 a.m.

Place: Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443-1000.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.