

These provisions apply the concept of a court decision to the timing of certain ANDA approvals and to the start of 180-day exclusivity. There is a 30-month statutory bar to approval of an ANDA that is the subject of patent infringement litigation except if "before the expiration of such period the court decides that such patent is invalid or not infringed, the approval will be made effective on the date of the court decision" (section 505(j)(5)(B)(iii)(I) of the act (21 U.S.C. 355(j)(5)(B)(iii)(I))). Certain court decisions are also important for 180-day generic drug exclusivity. The 180-day period of exclusivity can begin on either: (1) The date of first commercial marketing, or (2) the date of a decision of a court holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed, whichever is earlier (section 505(j)(5)(B)(iv) of the act). For purposes of section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act, FDA determined that "court" means "the court that enters final judgment from which no appeal can be or has been taken" (§ 314.107(e)(1) (21 CFR 314.107(e)(1)) (1999)).

FDA's interpretation of the term "court" has been successfully challenged in the context of both the timing of ANDA approvals and the commencement of 180-day exclusivity. These recent decisions add considerable uncertainty to FDA's implementation of the ANDA approval and 180-day generic drug exclusivity programs. Therefore, in determining its response to the *TorPharm* and *Mylan* decisions, a primary concern for the agency has been to identify an approach that will minimize further disruption and will provide the regulated industry with reasonable guidance for making future business decisions. The government has decided not to appeal the *Mylan* decision and will follow that court's interpretation of the statute in approving ANDA's and calculating the commencement of 180 days of exclusivity. The agency intends to formally amend § 314.107(e) and will incorporate the *TorPharm* and *Mylan* courts' interpretation of the statute into the final rule implementing the changes in 180-day exclusivity (64 FR 42873, August 6, 1999). FDA will implement the new interpretation of the term "court" prospectively.

FDA will interpret the term "court" as found in section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act to mean the first court that renders a decision finding the patent at issue invalid, unenforceable,

or not infringed. The new definition of "court" will be applied to approval and exclusivity determinations for all ANDA's containing a paragraph IV certification submitted after the publication of this guidance, where the ANDA cites a reference listed drug for which no other ANDA containing a paragraph IV certification has been submitted.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance is being implemented immediately without prior public comment because the guidance is needed to explain FDA's application of the statute in light of recent court decisions. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on section 505(j)(5)(B)(iii)(I) and (j)(5)(B)(iv) of the act. 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 act.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). 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 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.

Dated: March 23, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0805]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent Requirements for Emergency Research; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research." The draft guidance document provides guidance for developing and implementing research in emergency settings when an exception from the informed consent requirements is requested under the Food and Drug Administration's (FDA's) emergency research rule.

DATES: Written comments on the draft guidance document are to be submitted by May 30, 2000. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research" to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Bonnie M. Lee, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0415

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research." In the **Federal Register** of October 2, 1996 (61 FR 51498), FDA published regulations that provide a narrow exception to the requirement for obtaining and documenting informed consent from each human subject, or his or her legally authorized representative, prior to initiation of an experimental intervention (§ 50.24 (21 CFR 50.24) in part 50 (21 CFR part 50)). The exception

would apply to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. The preamble to part 50 stated that the agency intends to monitor and evaluate the implementation of these regulations on an ongoing basis. Since the effective date of these emergency research regulations (November 1, 1996), FDA has reviewed the efforts of sponsors, Institutional Review Boards, and clinical investigators to interpret and comply with these regulations and has determined that guidance is needed.

The draft guidance document, available for public comment, addresses issues pertinent to the implementation of FDA's emergency research regulations. The draft guidance document provides guidance on the development and conduct of community consultation and public disclosure activities; the establishment of informed consent procedures to be used when feasible; the need for the concurrence of a licensed physician; use of data monitoring committees; use of independent IRB's; documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study; and other aspects of the emergency research regulations.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on ways to effectively implement its emergency research regulations in order to protect the rights and welfare of human subjects participating in that research. 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 and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information contained in the guidance document may be applicable to all situations.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the

docket number found in the brackets in the heading of this document. A copy of the draft guidance document 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. Electronic Access

Persons with access to the Internet may obtain the document using the Internet at http://www.fda.gov/ora/compliance_ref/bimo/default.html.

Dated: March 21, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-7778 Filed 3-29-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-295]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Medicare CAHPS Disenrollment Survey; *Form No.:* HCFA-R-295 (OMB 0938-0779);

Use: This survey is used to collect information from Medicare beneficiaries who have disenrolled from their health plans during the past year. The purpose of this information is to obtain their

ratings of their former plans and the reasons why they left. The survey results will be reported to all beneficiaries in print and on the Internet for the purpose of informed choices. Secondary uses of survey results include quality improvement and contract oversight;

Frequency: Quarterly, Annually; *Affected Public:* Individuals or Households;

Number of Respondents: 112,800;

Total Annual Responses: 90,240;

Total Annual Hours: 39,744.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 20, 2000.

John P. Burke III

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-7905 Filed 3-29-00; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Withdrawal

AGENCY: Health Resources and Services Administration.

ACTION: Notice; withdrawal.

SUMMARY: In the **Federal Register** notice of Wednesday, August 18, 1999, in FR Doc. 99-21257, on page 45025, the grant category beginning in the third column under the heading "State and Local Data Utilization and Enhancement (DUE) Cooperative Agreements, CFDA# 93.110U," is withdrawn from competition because of insufficient funds to support the full scope of