TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE OCTOBER 1, 1999, THROUGH DECEMBER 31, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970010/99M–4361	Synthes (USA)	Norian Skeletal Repair System (SRS) Cancellous Bone Cement	December 23, 1998
P970015/99M–4277	Sofamor Danek	Inter Fix Threaded Fusion Device	May 14, 1999
P960033/99M–4693	Staar Surgical	Staarvisc™ Sodium Hyaluronate	July 2, 1999
P980053/99M–4278	Advanced Uroscience, Inc.	Durasphere Injectable Bulking Agent	September 13, 1999
P990008/99M–4276	Cook, Inc.	Cook MBC PTCA Balloon Dilatation Catheter	September 27, 1999
P990001/99M–4281	Vitatron, Inc.	Diva Platform Implantable Pulse Generators & Pro Vit Application Software Version 3.3.2	September 27, 1999
P990020/99M–4331	Medtronic Aneurx	Aneurx Stent Graft System	September 28, 1999
P980043/99M–4279	Medtronic, Inc.	Hancock II Bioprosthetic Heart Valve	September 28, 1999
P990017/99M–4280	Guidant Cardiac & Vascular Surgery	EVT Abdominal Aortic Tube/EVT Abdominal Aortic Bifurcated EGS System	September 28, 1999
P990004/99M–4776	Ethicon, Inc.	Surgifoam Absorbable Gelatin Sponge, USP	September 30, 1999
P940034 (S008)/99M–4782	Gen-Probe, Inc.	Gen-Probe® Amplified Mycobacterium Tuberculosis Direct Test (MTD Test)	September 30, 1999
P990002/99M-4330	Rochester Medical Corp.	Femsoft Urethral Insert	September 30, 1999
H980007/99M–4810	Shelhigh, Inc.	Shelhigh Pulmonic Valve Conduit Model NR–4000 with ''No-React®'' Treatment	September 30, 1999
P990033/99M–4692	Ceramed Corp.	PepGen P–15	October 25, 1999
P990014/99M–5135	Bausch & Lomb Surgical, Inc.	Hydroview Composite Hydrogel Foldable UV–Absorbing Posterior Chamber Intraocular Lens	November 12, 1999
H990007/99M–5327	CryoLife, Inc.	BioGlue® Surgical Adhesive	December 7, 1999
H980006/99M–5539	MDS Nordion, Inc.	TheraSphere®	December 10, 1999

Dated: March 14, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–7780 Filed 3–29–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1197]

Guidance for Industry on Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' The purpose of this guidance is to inform the public of FDA's application of the abbreviated new drug application (ANDA) approval provisions and 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on these issues.

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

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' This guidance is being issued in response to recent litigation. The guidance is intended to provide information to the pharmaceutical industry regarding: (1) The timing of approval of ANDA's following an unsuccessful patent infringement action by the patent owner or new drug application (NDA) holder and (2) the start of 180 days of generic drug exclusivity.

FDA's interpretation of two provisions of the act have been successfully challenged in *TorPharm, Inc.* v. *Shalala* and *Mylan Pharmaceuticals, Inc.* v. *Shalala* [1].

[1] *Torpharm* v. *Shalala*, No. 97–1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. September 15, 1997); *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. February 5, 1998); *vacated* No. 97–1925 (D.D.C. April 9, 1998); *Mylan*

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.

[FR Doc. 00–7823 Filed 3–29–00; 8:45 am]

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Pharmaceuticals, Inc. v. *Shalala,* No. 99–2995, slip op. (D.D.C. January 4, 2000).

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