$286,750 per application not requiring clinical data or per supplement requiring clinical data.

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of PDUFA, as amended, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (see 21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in PDUFA fee revenue. To date, collections for FY 1998 total $117,737,470—a total of $615,470 in excess of the appropriation limit. This is the only fiscal year since 1997 in which FDA has collected more in PDUFA fees than Congress appropriated.

FDA also has some requests for waivers or reductions of FY 1998 fees that have been decided but that are pending appeals. For this reason, FDA is not reducing its FY 2004 fees to offset excess collections at this time. An offset will be considered in a future year, if FDA still has collections in excess of appropriations for FY 1998 after the pending appeals for FY 1998 waivers and reductions have been resolved.

V. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2003, the establishment fee was based on an estimate that 354 establishments would be subject to and would pay fees. By the end of FY 2003, FDA estimates that 379 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA again estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2003, for a net of 354 fee-paying establishments. FDA will use this number, 354, for its FY 2004 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($80,287,900) by the estimated 354 establishments, for an establishment fee rate for FY 2004 of $226,800 (rounded to the nearest one hundred dollars).

B. Product Fees

At the beginning of FY 2003, the product fee was based on an estimate that 2,293 products would be subject to and pay product fees. By the end of FY 2003, FDA estimates that 2,260 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. Assuming that there will be about 35 waivers and reductions made, FDA estimates that 2,225 products will qualify for product fees in FY 2003, after allowing for waivers and reductions, and will use this number for its FY 2004 estimate. Accordingly, the FY 2004 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($80,287,900) by the estimated 2,225 products for a FY 2004 product fee of $36,080 (rounded to the nearest ten dollars).

VI. Fee Schedule for FY 2004

The fee rates for FY 2004 are set out in table 4 of this document:

TABLE 4.

FEE CATEGORY	FEE RATES FOR FY 2004
APPLICATIONS	
Requiring clinical data	$573,500
Not requiring clinical data	$286,750
Supplements requiring clinical data	$286,750
ESTABLISHMENTS	$226,800
PRODUCTS	$36,080

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is submitted after September 30, 2003. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee identification (ID) number on your check. Your check can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: Food and Drug Administration (360909), Mellon Client Service Center, rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This Mellon Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 360909) is on the enclosed check. The tax ID number of the FDA is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2003, FDA will issue invoices for establishment and product fees for FY 2004 under the new Fee Schedule. Payment will be due on October 1, 2003. FDA will issue invoices in October 2004 for any products and establishments subject to fees for FY 2004 that qualify for fees after the August 2003 billing.

Dated: July 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19654 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0325]

Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day; 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 ''180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.'' This guidance explains how FDA intends to determine eligibility for 180-day exclusivity when multiple substantially complete abbreviated new drug applications (ANDAs) that contain a paragraph IV certification to the same

patent(s) are submitted on the same day or when paragraph IV certifications are submitted in an amendment or supplement on the same day.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Cecelia Parise, Center for Drug Evaluation and Research (CDER) (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.'' This guidance document provides information to sponsors and/or applicants regarding how the agency intends to determine eligibility for 180-day exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 355(j)(5)(B)(iv)) when multiple ANDA applicants submit a paragraph IV certification to a listed patent on the same day and no paragraph IV certification to the patent has been submitted on any previous day.

A. Statute and Regulations

A new drug application (NDA) applicant must include in its NDA information about any patents that claim the drug product that is the subject of the NDA or the use of such drug product (section 505(b)(1) and (c)(2) of the act). FDA publishes this patent information upon approval of the NDA or a supplemental NDA in ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.''

An ANDA applicant must include in its ANDA a patent certification as described in section 505(j)(2)(A)(vii) of the act. The certification must make one of the following statements: (1) Such patent information has not been filed; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a paragraph IV certification. The ANDA applicant must provide appropriate notice of a paragraph IV certification to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers (section 505(j)(2)(B)(i) of the act (part 314 (21 CFR part 314))).

The act provides an incentive for generic drug manufacturers to file paragraph IV certifications and challenge listed patents as invalid or not infringed, thereby permitting generic drugs to reach the market more quickly. Section 505(j)(5)(B)(iv) of the act provides for a 180-day period of marketing protection for certain ANDA products as follows:

> If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after-
>
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
>
> (II) the date of a decision of a court in [a patent infringement action] holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier (emphasis added).

The statute does not further define the phrase ''for which a previous application has been submitted.'' In its regulation at § 314.107(c), FDA uses both the terms ''previously submitted'' and ''first'' in implementing this provision of the statute. It adopts the phrase ''for which one or more substantially complete abbreviated new drug applications were previously submitted'' to restate the conditions under which exclusivity will apply. The regulation at § 314.107(c)(1)(i) states that exclusivity may begin to run from ''[t]he date the applicant submitting the first application first commences commercial marketing of its drug product.'' The phrase ''applicant submitting the first application'' is defined in the regulation as ''the applicant that submits an application that is both substantially complete and contains a certification that the patent was invalid, unenforceable, or not infringed prior to the submission of any other application for the same listed drug that is both substantially complete and contains the same certification.'' (§ 314.107(c)(2)) Thus, the agency has adopted the terms ''previous,'' ''first,'' and ''prior'' to identify the ANDA eligible for exclusivity. However, the agency has not elaborated on how these terms should be applied when more than one applicant submits a paragraph IV certification to the same patent on the same day.

B. 180-Day Exclusivity and Different Day Patent Certifications

The statute and the regulations at § 314.107(c) are straightforward to apply when ANDAs, amendments, or supplements are submitted to FDA on different days. An ANDA submitted on the day before another application is submitted, when no application has been submitted on an earlier day, is clearly the ''previous,'' the ''prior'' and the ''first'' application. To date, FDA's exclusivity decisions have involved applications or amendments submitted on different days, and thus have not required additional interpretation of the statute or regulations on this point.

Recently, FDA has had to consider how to apply the 180-day exclusivity provision when multiple challenges to the same patent are submitted on the same ''first'' day. After the decisions in *Mova Pharmaceuticals, Inc.* v. *Shalala*, 140 F.3d 1060 (D.C.Cir. 1998) and *Granutec, Inc.* v. *Shalala*, 46 U.S.P.Q.2d 1398 (4th Cir. 1998), the first applicant who submits a substantially complete ANDA containing a paragraph IV certification to a listed patent is eligible for 180-day generic drug exclusivity.[1] As noted in a 1999 citizen petition response,[2] many of the current regulations were adopted prior to the *Mova* decision, when the agency interpreted the statute to require that an ANDA applicant had to be sued and win its patent litigation to qualify for 180-day exclusivity. FDA's pre-*Mova* interpretation limited the number of times 180-day exclusivity was awarded because an ANDA applicant had to be first to challenge a patent and then win the patent litigation to be eligible for 180-day exclusivity. The chance of

[1] The regulatory history of this issue has been previously described in the June 1998 CDER guidance for industry entitled ''180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendment to the Federal Food, Drug, and Cosmetic Act.''

[2] See response to 99P–1271/PSA1 and PSA2 issued August 2, 1999.

having multiple ANDA applicants qualify for 180-day exclusivity was extremely low, as evidenced by the number of times that 180-day exclusivity was granted.[3] By contrast, after the *Mova* decision, it is now relatively easy to qualify for 180-day exclusivity. As a result, FDA has had to address a number of new issues, including eligibility for exclusivity when multiple paragraph IV certifications are submitted on the same day.

Congress did not address the possibility that multiple applicants would submit patent challenges to FDA on the same day in the 180-day exclusivity provisions of the act. Similarly, FDA regulations now in effect do not address this specific situation. However, in an August 1999 proposed rule addressing 180-day exclusivity issues, FDA proposed an approach whereby all applicants submitting a paragraph IV certification to a patent on the first day such a certification is submitted are ''first applicants'' for 180-day exclusivity purposes (64 FR 42873, August 6, 1999). FDA received comments both for and against this approach (see Docket No. 85N–0214). The August 1999 proposed rule was withdrawn in November 2002 for reasons unrelated to the merits of the multiple first applicant approach (67 FR 66593, November 1, 2002). When the proposed rule was withdrawn, the agency noted it would continue to regulate directly from the statute and any applicable regulations, and make decisions on an issue-by-issue basis. The agency continues to believe that the approach to multiple first day patent challenges described in the proposed rule is a reasonable and appropriate interpretation of the statute. Two citizen petitions have specifically asked the agency to follow the approach described in the proposed rule when addressing 180-day exclusivity in cases where there are multiple ANDAs containing challenges to the same patent(s) submitted on the same day (see Docket Nos. 00P–1445 and 03P–0217).

Same day patent challenges generally occur when the expiration of 4 years of a 5-year exclusivity period under section 505(j)(5)(D)(ii) of the act permits submission of ANDAs containing a paragraph IV certification as of a specific date, and multiple applicants vie to be first to make such a submission. Multiple submissions on the same day may also occur when a new patent is issued by the Patent and Trademark Office and submitted to FDA by the NDA sponsor after ANDAs have been submitted. Because new patents must be submitted to FDA within 30 days of issuance, ANDA applicants position themselves to be the first to submit a paragraph IV certification as soon as the patent is submitted to FDA, often exactly 30 days after patent issuance.

Implementation of a rule that determined eligibility for 180-day exclusivity by the minute or second of submission would be problematic for several reasons. First, applications arrive at CDER by different means and at different locations. They are delivered by U.S. mail, delivery service, courier, and in person by the applicant or its agent.[4] They may be delivered to mailrooms at FDA's Parklawn Bldg. or at its Metro Park North Bldg., which have different zip codes and are miles apart (§ 314.440). Second, when multiple ANDAs are delivered to the mailrooms on the same day, there is no effective way to determine in what order the documents were submitted. Also, when more than one application is present in a given delivery, the order in which the applications are date-stamped by the document room is random and reflects only the application's arbitrary place in the pile of mail. Moreover, a submission delivered to the agency early in the day may, in fact, be date-stamped after a submission delivered later in the day because the former submission was underneath the latter in the mail pile. Third, some ANDA applicants have assumed that hand delivery would be the best way to secure the ''first'' application slot. Applicants have arrived outside of an FDA-occupied building on or before the date on which ANDAs may be submitted. Recently, there have been a number of cases in which multiple ANDA applicants or their representatives have camped out adjacent to an FDA-occupied building for periods ranging from 1 day to more than 3 weeks to await the first date on which applications could be submitted to the agency. FDA does not have a system for determining which of those multiple applicants who are present either before the date of submission, or at 12:01 a.m. on the date of submission, or when FDA opens its doors to receive submissions, should be considered ''first.'' The order of applicants in a line that has formed before applications may be submitted is as random as the location of an application in a pile of mail in the mailroom.

Where multiple applicants are simultaneously present to submit patent certifications on the first day that such submissions are made, rewarding only the first applicant in line does not further any of the goals of the Hatch-Waxman amendments. Even if it were reasonable to argue that someone who is willing to stand in line for days or months should benefit by being considered the first to submit a patent challenge, security and other concerns have foreclosed that option.

The agency can no longer permit applicants to line up outside FDA-occupied buildings in advance of the date ANDA submissions are permitted. For example, when an applicant arrived outside of the FDA-occupied building in mid-May 2003 to establish first place for a number of ANDA submissions, one of which could not be submitted until mid-December 2003, the owner of the government-leased building informed FDA in a June 4, 2003, letter that the 24-hour presence of the pharmaceutical company representatives violated the policy described in the rules and regulations governing the use of the property. In addition, the owner noted its serious liability concerns regarding safety and security. Because of the owner's concerns, FDA directed the waiting ANDA applicant representative to leave the premises.

Furthermore, measuring submissions by the minute or second would be inconsistent with CDER's general administrative practices. CDER conducts its business by calendar day, not by the hour, minute, or second. For example, NDA review times under the Prescription Drug User Fee Act are based upon the date an application was submitted, and approvals are effective as of the date of the issuance of the approval letter (§ 314.105). In addition, 180-day exclusivity runs for 180 calendar days from the date of a commercial marketing or court decision triggering event, without regard to the precise time of day the exclusivity was triggered (§ 314.107(c)(1)). CDER considers most documents, including NDAs, ANDAs, and application amendments and supplements, to have been submitted to FDA as of the date-stamped on the document by the appropriate CDER document room.

In considering how to apply the 180-day exclusivity provisions to multiple patent challenges, FDA reviewed a number of possible approaches. First, the agency examined whether there was a safe and practical way to determine whose patent challenge is actually submitted to the agency first. The only

[3] In the years from 1984 to 1998, only three ANDA applicants qualified for 180-day exclusivity. Since the *Mova* decision in 1999, more than 60 ANDAs have received 180 days of exclusivity.

[4] FDA does not consider submission by facsimile or e-mail official for purposes of determining the date of submission.

way to ensure the order of submission would be to require all submissions to be made in person, with the establishment of some kind of monitored line. The owner of the FDA-occupied building has given the agency the option of permitting applicants to line up outside the building at 12:01 a.m. on the morning submissions may be accepted. However, such lines would raise issues of security and fairness for applicants and could lead to evidentiary disputes over which applicant, if any, was in line first. FDA is already aware of at least one instance in which an applicant videotaped its arrival on government property in an attempt to document that it was first to submit a patent challenge. Thus, this approach could lead to administrative proceedings and litigation over tie-breaking virtually simultaneous submissions. In addition, such an approach would disadvantage applicants who do not make submissions in person, because mail deliveries are likely to be made to FDA after the door opens for in person submissions.

The agency also considered requiring submission by mail and then date- and time-stamping submissions based on the order they were processed by the mailroom and document room. This approach would require FDA to determine, from among the various submissions made in the same delivery, which submission was first, itself an arbitrary process. Is the first submission the first ANDA to be removed from the mail bag, or the document on top of the pile after the mail is removed from the delivery container?

The agency even considered adopting a lottery approach, in which one ANDA would be chosen at random from among all the eligible ANDAs submitted on the same first day. This approach, although appealing in its simplicity and no less random than mail delivery or an applicant's place in line, has no support in the statute.

Finally, FDA considered permitting submission by facsimile. However, this approach raises many practical concerns involving after-hours submissions, jammed fax machines, and disputes over submission order. In sum, all of these approaches were rejected because they raise safety concerns, are administratively unworkable, or would arbitrarily and unfairly distinguish between similarly situated applicants. In addition, none of them addresses the fundamentally arbitrary nature of declaring any one patent challenge made on a certain day to be previous to all other challenges made on that day.

C. 180-Day Exclusivity and Multiple Same Day Patent Challenges

FDA intends to interpret the phrase ''for which a previous application has been submitted'' in section 505(j)(4)(B)(iv) of the act to mean an ANDA that has been submitted on a previous day. Thus, when multiple ANDAs containing paragraph IV challenges to patents are submitted to FDA on the same day—and no paragraph IV certification to that patent has been submitted on a previous day—FDA intends to consider none of the patent challenges to be previous to other challenges to the same patent submitted on the same day and all of those challenges as previous to paragraph IV certifications to the same patent submitted on a subsequent day. This is the general interpretation described in the 1999 proposed rule.

Under this approach, all of the applicants submitting substantially complete ANDAs, amendments, or supplements containing a paragraph IV certification for a listed patent on the same first day would be eligible for 180-day exclusivity. That exclusivity would begin to run for all of the applicants eligible for 180-day exclusivity from the earlier of the initial commercial marketing of the drug by any of the first applicants or by a court decision finding the specific patent as to which the applicants were first to file paragraph IV certifications invalid, unenforceable, or not infringed. During the exclusivity period, FDA may approve any other first applicant's ANDA, but no other ANDAs. Any first applicant's ANDA approved after the exclusivity has been triggered will share in the remaining period of exclusivity. Once the 180-day exclusivity period has run, FDA may approve all subsequent ANDAs.

The agency believes that this exclusivity approach is consistent with the statutory language in that, under at least one reasonable reading of section 505(j)(5)(B)(iv) of the act, none of the applications submitted on the same day is ''previous'' to any other application submitted on the same day, and all applications submitted on the same day are previous to any application submitted on any day thereafter.

This interpretation is also consistent with the intent of both the 180-day exclusivity provision, in particular, and the Hatch-Waxman Amendments, in general. Instead of giving exclusivity to a single applicant who may be first only by dint of jockeying for a better place in line, or by the happenstance of location within a pile of mail, this approach recognizes that all of the applicants who challenged a patent on the first day such a challenge is submitted challenged the patent at essentially the same time, and rewards them accordingly.

The approach maintains the incentive to be first to submit a patent challenge but, in the case where there are multiple applicants submitting patent challenges on the same first day, it will provide an equal chance at the benefits of exclusivity to all of those applicants. The approach will also provide the opportunity to be the sole beneficiary of exclusivity if an applicant obtains approval of its ANDA and begins to market at least 180 days before any of the other first applicants begins to market.

Finally, this approach will permit applicants to submit ANDAs by U.S. mail, courier, delivery service, or in person on a more reasonable timetable; preserve the safety and security of the applicants and FDA property and staff; and prevent time-consuming disputes over ''who's first,'' which rely on video and other evidence.

This guidance is being issued as a level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The agency believes that given the need for public guidance on this pressing issue and existing liability, safety, and security concerns, public comment is neither feasible nor appropriate before implementing this guidance. Comments on the guidance are welcome at any time.

FDA intends to implement this approach immediately for all applicable 180-day exclusivity determinations made by FDA on or after the date of the notice announcing the availability of this guidance (including for patent certifications that were submitted prior to the date of the notice where the exclusivity determination has not yet been made). The approach described in this guidance will remain in effect until superseded. As noted in this section I, to date, FDA's exclusivity decisions have only involved applications or amendments submitted on different days.

This guidance represents the agency's current thinking on 180-day exclusivity when multiple ANDAs are submitted on the same day. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic

comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19590 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0228]

Medical Devices; Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device.'' This guidance document represents the agency's current thinking on the technical content and clinical considerations for a premarket approval application (PMA) for an implantable middle ear hearing device (IMEHD). This guidance provides information to consider for developing the clinical studies and generating the scientific evidence that will provide reasonable assurance of safety and effectiveness of the IMEHD for its intended use.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Industry and FDA; Implantable Middle Ear Hearing Device'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080, ext. 187.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 12, 2002 (67 FR 40318), FDA announced the availability of the draft guidance entitled ''Guidance for Industry and FDA; Implantable Middle Ear Hearing Device.'' FDA invited interested persons to comment on the draft guidance by September 10, 2002. On August 16, 2002, FDA held a meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee to discuss the draft guidance.

FDA received seven comments. In general, most comments suggested various clarifications throughout the document. FDA revised the document accordingly. One comment stated that the standard entitled ''ANSI/IEEE C63.19–2001 American National Standard for Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids'' was developed for air conduction hearing aids and that the standard requires measurements that have been difficult to reproduce in these conventional hearing aids. FDA agrees, however, the agency believes that portions of this standard may be useful. Therefore, the guidance has been revised to recommend that manufacturers use test methods cited in this standard that are applicable to their device designs. There were two comments requesting a more precise definition for the ''control condition'' in the suggested clinical study design for IMEHDs. FDA agrees and will replace the term ''state-of-the-art'' with ''appropriately fit conventional air conduction hearing aids.'' Another comment suggested that measuring aided baseline performance is not necessary as a control condition. FDA disagrees. The agency believes that it is important to compare IMEHD performance to both appropriately fit conventional air conduction hearing aid performance and unaided performance for the benefit of clinicians and prospective IMEHD recipients.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on premarket approval applications for IMEHDs. 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 and regulations.

III. Electronic Access

To receive ''Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1406) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to