1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

February 7, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Medical Device User Fee and Modernization Act of 2002 (MDUFAMA)
Docket Number: 02N-0534

In response to the Food and Drug Administration's (FDA's) request that stakeholders provide comments on specific provisions of MDUFMA, AdvaMed, the Advanced Medical Technology Association, is providing comments on the Premarket Approval (PMA) modular review program (section 209 of MDUFMA). AdvaMed represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

AdvaMed's comments on the PMA modular review program focus on the following areas:

1. Scope of application of modular review
2. Performance goals related to review of modules
3. Collection of user fees for modular submissions

1. Scope of application of modular review

Although the agency has stated its intent to limit modular review to original PMA submissions, AdvaMed recommends that the scope of the modular program include Panel-track Supplements and certain 180-day Supplements. AdvaMed believes that modular review should be permitted for supplements containing clinical data where the expected duration of the clinical trial is sufficient to allow reasonable time for the submission and closure of preclinical modules.

02N-0534 C 8

- *Pannel Track Supplements*:
  These supplements for new indications or significant changes in design or performance require substantial clinical data to support the determination of a reasonable assurance of safety and effectiveness. A panel track supplement typically contains an amount of clinical data equivalent to that in the original PMA. In addition, such supplements usually contain significant preclinical testing that could be reviewed at an earlier stage using the modular process. Finally, a panel track supplement is subject to the same user fee as an original PMA and therefore, AdvaMed believes that modular review should be available to panel track supplements to ensure consistency and equity in the user fee program.

- *180 Day Supplements*
  Some 180-day supplements include clinical data, especially for a next generation update of the original PMA device. The clinical data is generally of a lesser extent than that in the original PMA. These supplements will also contain significant preclinical testing that could be reviewed at an earlier stage using the modular process. If the expected duration of the clinical trial is long enough that it offers the reasonable potential for modules to be reviewed and closed prior to the PMA submittal, AdvaMed believes that the agency should accept them for modular review. Because the agency has established in its current Modular Review Guidance a goal of 90 days for the review and closure of modules, AdvaMed believes that the agency will have sufficient time to review and close pre-clinical modules where the expected clinical study duration is 6 months or longer.

- *Process*
  In the initial stages of the modular review process, FDA first reviews the PMA shell which is the outline of the modules that will be completed and submitted prior to the submission of the full PMA application. At this time, FDA has the information to determine the appropriateness of modular review for that supplement. Because the sponsor submits the user fee at the time of submission of the first module, any frivolous use of modular review will be minimized.

FDA is in the process of revising its PMA Modular Review guidance document and we believe that the revision should include these changes. AdvaMed also recommends that FDA develop a Frequently Asked Questions section to include in the document and we offer our assistance in this effort.

2. Performance Goals related to modular review

In the current PMA Modular Review Guidance document, FDA established a goal of 90 days to review and close modules where the information submitted in the module was complete. AdvaMed believes that this is an acceptable goal. However, when the information submitted is not sufficient and FDA requests additional information from the sponsor, AdvaMed proposes that such communications to the sponsor occur within 75 days of filing the module. Once the sponsor responds to the agency's request for additional information, AdvaMed proposes that the agency close the module within 90 days. AdvaMed would like to offer our assistance in working out the specifics related to these proposed goals for modular review.

3. Collection of user fees for modular submissions

Section 209 of MDUFMA amended section 515(c) of the Federal Food, Drug and Cosmetic Act to state:

> Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(g), the Secretary does not have the authority to collect fees under section 738(a).

See § 515(c)(3)(A) of the Act. Specifically, section 209 codified the Center for Devices and Radiological Health's ("CDRH's") modular review policy for premarket approval applications.

Section 102 of MDUFMA established the new device user fee program in sections 737 and 738 of the Act. Section 738(a)(1)(C) provides that fees shall be paid upon submission of PMAs, PMA supplements, premarket reports, and 510(k)s. It specifically provides for the payment of the whole PMA fee for a modular PMA at the time of submission of the first module.1 It therefore recognizes that receipt of a first module constitutes receipt of a portion

---

1 Section 738(a)(1)(C) states:

> The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission except that invoices for application submitted between October 1, 2002, and the date of enactment of the Medical Device User Fee and Modernization Act of 2002 shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 shall include all fees payable from October 1, 2002 through September 30, 2003.

of a PMA for review, triggering the requirement that the whole PMA fee be paid, just as the whole fee is due up front with the submission of whole PMAs. Thus, MDUFMA treats modular submissions the same as standard PMAs for purposes of fee assessment.

Like standard PMAs submitted prior to October 1, 2002, modular PMAs for which the initial module was submitted prior to that date are not subject to user fees

Because modular PMAs are treated the same as standard PMAs for purposes of triggering the requirement to pay a user fee, modular PMAs for which a module was submitted for review prior to October 1, 2002, should be treated the same as standard PMAs that were similarly submitted before that date, *i.e.*, no user fee should be required for such PMAs. Further, the submission of subsequent modules does not trigger fees under the Act anymore than the submission of an amendment to a PMA received by FDA before October 1, 2002, would require a user fee. The statute is clear that only the first module triggers a fee. *See* § 738(a)(1)(C) (fees for modular PMAs are due upon "submission of the first portion"). Moreover, under section 515(c)(3)(A) of the Act, the only time the Secretary has authority not to accept a module that the applicant and Secretary agree is ready for review is when the Secretary, under 738(g), does not have the authority to collect fees. Therefore, FDA has no authority to refuse review of post-October 1, 2002 modules when the first module was submitted prior to that date, unless the Secretary's authority to collect fees is suspended under section 738(g). Simply put, the refusal to pay user fees for PMA modules submitted after October 1 does not constitute a basis under the Act for the agency to refuse to accept such modules for review or to refuse to review the whole PMA application when submitted to the agency.

Retroactive application of device user fees to modular PMAs first submitted before October 1, 2002, is illegal and upsets applicants reasonable expectations

Furthermore, to subject new modules, and/or complete PMAs for which modules were submitted before the effective date of user fees, to a user fee would be an illegal retroactive application of the law. Absent express authorization in a federal statute, there is a presumption against applying a statute retroactively. *Landgraf v. USI Film Products*, 114 S. Ct. 1483 (1994). Indeed, if a statute expressly mandates its temporal reach, courts follow Congress's express wishes. *Id.* at 1494, 1505. Here, the legislation expressly makes the effective date of the user fee portion of legislation October 1, 2002, the first day of fiscal year 2003, which is the first fiscal year in which device user fees apply:

> The amendments made by this title shall take effect on the date of enactment of this Act, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002, regardless of the date of enactment.

Section 106 of MDUFMA; *see also* H.R. Rep. No. 107-728 at 24 (2002) ("Fees will be assessed for all applications submitted on or after October 1, 2002."). In contrast, nowhere in MDUFMA does Congress expressly require fees from modular PMA applicants, or any other applicants, who made submissions prior to October 1, 2002.

Indeed, recognizing that some applications may have been submitted after October 1, but prior to the enactment date, the legislation specifically provides that fees for such applications must be paid by October 30. *See* § 738(a)(1)(C). No such accommodations were made for modular review submissions, or any other user fee submissions, that were first submitted before October 1. Therefore, while Congress clearly intended that the fees be retroactive for certain submissions to FDA after the beginning of fiscal year 2003, it drew the line at the beginning of the fiscal year, October 1. MDUFMA did not make special arrangements for PMAs or other submissions to FDA that occurred prior to October 1 because Congress did not intend to subject such submissions to user fees.

Because there is no basis in the law or legislative history to suggest Congress intended a retroactive application of device user fees to premarket submissions made prior to October 1, any action by FDA to require fees from modular PMA applicants that submitted the initial module before October 1 is illegal. Moreover, like standard PMA applicants who submitted applications before October 1, modular PMA applicants who submitted their first module before that date had reasonable business expectations that they would not be subject to user fees. A retroactive application of fees would therefore be unfair as well as illegal. *See Landgraf*, 114 S. Ct. at 1499 (unlawfully retroactive applications of statutes upset "familiar considerations of fair notice, reasonable reliance, and settled expectations").

In sum, neither the plain language of the statute nor the settled case law on retroactive application of statutes supports charging user fees to modular applicants who submitted their first module for review prior to October 1, 2002.

AdvaMed appreciates the opportunity to provide these comments and would like to work with the agency to ensure the appropriate implementation of this key provision of MDUFMA.

Sincerely

Janet Trunzo

Janet Trunzo
Vice President
Technology and Regulatory Affairs