

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

Elizabeth D. Jacobson, Ph.D.
Executive Vice President
Technology and Regulatory Affairs
Direct: 202 434 7220
ejacobson@AdvaMed.org



February 24, 2004

Joanne Less, Ph.D.
Investigational Device Exemption Section
FDA/CDRH/ODE (Room 130F)
9200 Corporate Boulevard (HFZ-403)
Rockville, MD 20850

Dear Joanne:

This is a follow-up to the January 26 conference call that Janet Trunzo and I had with you and other FDA representatives (Beverly Rothstein, Dan Shultz, Heather Rosecrans, Phil Philips) to discuss 510(k) performance goals under the Medical Device User Fee and Modernization Act (MDUFMA) and the collection of fees for administrative actions related to 510(k) submissions.

During the call, FDA posed the following questions:

1. Should FDA include decisions other than SE/NSE in the calculation of performance goals for 510(k)s under MDUFMA?
2. Should FDA retain fees collected for 510(k) submissions when the product is exempt from a submission or is deemed not a device or a general purpose article or a transitional device?

We responded to your questions with the following:

1. Only SE and NSE decisions should be included in the performance goal measurements for 510(k)s under MDUFMA.
2. FDA should refund any fees collected for 510(k) submissions when FDA determines that a submission was not required.

February 24, 2004

To further substantiate our responses to you during the call, we have attached a legal analysis of the appropriate sections of MDUFMA. If, after review of the attached information, you would like to discuss this further, we are available to meet with you. Thank you for giving us the opportunity to respond to your questions related to the implementation of MDUFMA. We look forward to opportunities for open discussions with you as future implementation issues arise.

Sincerely,



Elizabeth D. Jacobson, Ph.D.

Enclosure (1)

cc: Phil Philips (FDA)
Heather Rosecrans (FDA)
Beverly Rothstein (FDA)
Daniel Shultz (FDA)



FDA'S PROPOSED 510(K) USER FEE GUIDANCE

Issue: Whether administrative actions taken in the context of the 510(k) review process to remove inappropriate submissions from review, *e.g.*, submissions for devices that are exempt from premarket notification, general purpose articles or transitional devices, should be covered by 510(k) user fees and considered a “decision” for user fee goals purposes.

Response: No.

Discussion: User fees are only available to support certain activities defined by MDUFMA, and in the premarket notification area, both the law and the agency’s Goals Letter signed by the Secretary support the conclusion that FDA should not be compensated for administrative determinations that conclude that a device is not subject to premarket notification. Additionally, administrative actions should not be included as decisions for user fee goal purposes.¹

Specifically, MDUFMA defines the term “process for the review of device applications” to mean any of a group of 12 listed agency activities “with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions: . . .” § 737(5) of the FD&C Act. Section 737(3) defines the term “premarket notification” to mean “a report submitted under section 510(k).” Placing the two definitions together, the most reasonable conclusion is that a user fee compensable activity is one in which the agency does something related to the substantive review of a 510(k) submission. In other words, if a person incorrectly submits a premarket notification, the agency’s administrative action to void the submission cannot be an activity “with respect to the review of a . . . premarket notification submission[]” because legally no premarket notification exists for agency review.

User Fee Legislation

The conclusion that only legally required premarket notifications are subject to user fees is supported by the specific circumstances that constitute the “process for the review of device applications . . . and premarket notification submissions,” *see* § 737(5), and the authorization for user fees under section 738. User fees are only authorized for specified submissions, and

¹ However, FDA has a reasonable argument to keep a user fee for a withdrawn 510(k) when the agency engages in a substantive review of a submission. However, only withdrawals where the agency notifies a submitter that it is prepared to issue an NSE letter should be considered a decision.

premarket notification submissions are among those submissions specified by the law. *See* § 738(a)(1)(A)(vii).

The “process for review” is defined by the activities set forth in section 737(5). The law contemplates that the process will include: the issuance of action letters; the inspection of manufacturing facilities undertaken as part of a review of a pending application; monitoring research “conducted in connection with the review of such applications, reports, supplements, and submissions; reviews of IDE/IND applications; the development of guidance “to improve the process for review of premarket applications, . . . and premarket notification submissions;” the development of test methods and standards “in connection with the review of such applications, . . . or submissions;” “[t]he provision of technical assistance to device manufacturers in connection with the submission of such applications, . . . or submissions;” any classification or reclassification, or device approval activity under section 515(b); the evaluation of “postmarket studies required as a condition of an approval;” and the compiling of data, etc. to identify safety and effectiveness issues “for devices subject to premarket applications, . . . or premarket notification submissions,” *see* § 737(5)(B) – (K), all of which relate to the actual review of submissions or activities that directly and affirmatively relate to the review process. None of these specified activities even resemble the administrative determination that a device is not legally subject to the 510(k) submission requirement. Indeed, removing premarket notification submissions for such devices from review is consistent with the reason submissions were not required in the first place, *i.e.*, the public health benefit of a review did not justify the expenditure of the agency’s premarket clearance resources to ensure reasonable assurance of safety or effectiveness, and why user fees are wholly inappropriate for submissions that FDA legally should not review.

Although section 737(5)(A) is a catchall, relating to “[t]he activities necessary for the review of premarket applications, . . . and premarket notification submissions,” it does not lend support to the conclusion that device submissions that are eliminated from the review queue, because the law does not require a premarket clearance, should be subject to user fees. To the contrary, even this general language makes clear that only “activities necessary for the review [of a submission]” are included within the “process for review of device applications, . . . and premarket notification submissions.” In other words, it would be unreasonable to conclude that removing an improperly submitted premarket filing from the review queue is “necessary for the review of [a premarket submission]” and thus subject to user fees. This conclusion, in context with the specific items appearing in paragraphs 737(5)(B)(B) through (K), fully supports the position that only activities related to the substantive review of devices are considered compensable under the user fee legislation. Importantly, device user fees authorized by section 738 are only available “to defray the increase in the costs of the resources allocated for the process for the review of device applications . . . over such costs . . . for fiscal year 2002 multiplied by the adjustment factor.” § 738(h)(2)(A)(ii). Said another way, only activities included in the “process of review of [premarket submissions]” are covered by user fees.

Goals Letter

Secretary Thompson’s “Goals Letter” is consistent with the above interpretation of the law. Nowhere in the letter, the type of premarket submission notwithstanding, is there even a

suggestion that user fees should be charged for submissions submitted to the agency without a legal basis. In the 510(k) user fee goals, the only activities identified in the Goals Letter as goals were action letters and decisions. The Goals Letter specifically defines what constitutes a decision in the context of premarket notification. The letter states, "For 510(k) submissions, issuance of one of the following letters is considered to be an FDA decision: 1. substantially equivalent (SE); 2. not substantially equivalent (NSE)." 148 Cong. Rec. S11,549, 11,550 (2002). Moreover, the letter specifically defines the other goals associated with 510(k), and limits them to "[f]irst action additional information letters" and "[s]ubsequent action letters." In other words, all goals reflect user fee activities related to substantively processing 510(k) reviews, not the elimination of submissions ineligible for such reviews.

Conclusion

Although the agency's interest is being paid for any activity undertaken in response to a premarket notification submission, neither the law nor the agency's commitments to tie its performance to funded activities, *e.g.*, premarket notification first and subsequent actions and SE/NSE decisions, include FDA's rejection of submissions because of the legal inappropriateness of conducting a 510(k) review. As a result, we believe that the FDA is incorrect in keeping user fee monies for rejecting submissions that are without a legal basis to permit a 510(k) review. Moreover, administrative actions not related to substantive 510(k) reviews should not be included in the agency's performance statistics to determine whether 510(k) user fee goals are met because such activities were neither intended to be covered by user fees nor were they identified in the Goals Letter.