DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 31, 2003 **General Program Memorandum #G03-1 (MDUFMA)**

From: Director, Office of Device Evaluation
Director, Office of In Vitro Diagnostic Device Evaluation & Safety

Subject: Section 206 of the Medical Device User Fee and Modernization Act (MDUFMA)
(New section 502(f) of the Federal Food, Drug, and Cosmetic Act)
Electronic Labeling for Prescription Devices Intended for Use in Health Care Facilities

To: ODE/OIVD Review Staff

Purpose

The purpose of this Blue Book Memorandum is to outline the responsibilities of the Office of Device Evaluation/ Office of In Vitro Diagnostic Device Evaluation & Safety (ODE/OIVD) in the proper implementation of Section 206 of MDUFMA and to provide instructions for fulfilling those responsibilities.

Background

Historically, the Food and Drug Administration (FDA) has required that all labeling for devices be provided to purchasers in "paper form." While this position has served the American consumer very well, it did not take into account the significant advances in information technologies that have occurred principally over the last 20 years and the benefits associated with the applications of these technologies. Advances in personal computers, combined with the development of the Internet, have fueled a widespread desire to go "paperless." The efficient and convenient storage of vast amounts of information, coupled with the ease of its retrieval, and the ability to better manage changing information, are just a few of the advantages that have prompted industries from around the world to provide information on their products in electronic "paperless" form. The medical device industry has been in the forefront of this technological revolution, attempting to satisfy the demands of its customers by offering product information through electronic means. Because of FDA requirements, however, any and all electronic copies of labeling had to also be provided to users in paper form.

Section 206 of MDUFMA amended Section 502(f) of the Federal Food, Drug, and Cosmetic Act (the Act) to authorize the use of electronic labeling, rather than the traditional paper labeling, under specified circumstances. Upon enactment, distributors of *prescription devices* who intend those devices to be used within the confines of a *health care facility* may provide labeling for those devices solely in electronic form, so long as they afford users the opportunity to request the labeling in paper form and promptly provide such labeling to requestors without additional cost.

It is important to recognize that FDA contributed to the language appearing in Section 206 of MDUFMA and was a strong advocate for updating the statute to reflect the progress that has transpired with information technology. Anticipating a likely continuation of this technology revolution, the new provision uses the term "electronic labeling," rather than specifying computer discs, computer diskettes, computer hard drives, or the Internet. This was done to ensure that the law allows for future change, as information technology progresses beyond what is known today.

The new provision of the law also addresses the concern that consumers without access to personal computers and the Internet would suddenly find themselves with devices and no readily available instructions for their use. Because Congress concluded that the greatest risk for this occurring was in the home, Section 206 stipulated that prescription (Rx) devices intended for use in health care facilities are the only devices that fall within the scope of the provision. By limiting the impact of the provision to Rx devices intended for use in health care facilities, it was understood that over-the-counter (OTC) devices would not be affected; neither would Rx devices intended for home use.[1] To address the concern that there may be health care facilities, such as physician's offices or small clinics, that may not have access to personal computers or the Internet, language was incorporated in the provision that assures such users an opportunity to request the labeling in paper form and *promptly* have such labeling provided *without additional cost*.

Lastly, Section 206 of MDUFMA does not exempt electronic labeling from any legal requirements that apply to device labeling in general. Manufacturers electing to provide electronic labeling must ensure that it is not false or misleading in any particular and are expected to meet all other applicable regulatory requirements, such as those contained in 21 CFR Parts 801 and 809.

Implications for ODE/OIVD

Section 206 eliminates the longstanding practice of requiring labeling for all devices to be provided to purchasers in paper form. This change in law will have direct and indirect consequences that will immediately impact ODE/OIVD.

First, scientific reviewers may prefer to access and review electronic labeling for certain devices when given the opportunity to do so. Although device companies should continue to provide paper labeling in all premarket submissions, on occasion we anticipate that submissions will also contain, or reference, the electronic labeling that is intended to be provided to purchasers.

Second, we recognize that many devices can be, and have been, configured to directly interface with personal computers and the Internet. To the extent that prior FDA labeling expectations have deterred such design, ODE/OIVD scientific reviewers may encounter more device designs that actually incorporate, or interface directly with, personal computers with Internet access capability.

[1] Health care practitioners may prescribe Rx devices for use by a patient in a home environment. The language in Section 206 of MDUFMA does not interfere with this practice.

General Principles

We believe that the content, clarity, and availability of labeling are far more important than the mode of transmission. To reduce the level of regulatory burden that could result from labeling changes related to Section 206 and to encourage the development of electronic labeling, we will minimize the requirements for implementing a shift to this type of labeling. In most cases, manufacturers need only document their performance of the necessary verification and validation activities associated with ensuring the proper design and function of their electronic labeling. As with all verification and validation activities relating to device design, manufacturers should maintain documentation of these activities in the design history file in accordance with the quality systems requirements.

For eligible devices that are the subject of approved premarket approval applications (PMAs), paper labeling may be transferred to electronic form and provided to health care facilities without approval of PMA supplements. PMA holders that implement this type of change should notify the agency of the change in the next annual report to the PMA. Similarly, changes from "paper form" to electronic form for eligible devices that are subject to 510(k) requirements may be implemented without the requirement to submit a 510(k).[2]

In the case of new Class III devices subject to premarket approval requirements, reviewers must insure that applicants intending to provide labeling to users strictly in electronic form are properly interpreting Section 206 eligibility, that is, the device is Rx and intended for use in a healthcare facility. The main purpose for this review is to ensure that FDA does not approve electronic labeling for an ineligible device. The Program Operations Staff will update the PMA filing checklist to remind ODE/OIVD staff of this responsibility.

In the case of premarket notification submissions (510(k)s), substantial equivalence (SE) determinations are not to be delayed by provisions of the Act that are unrelated to a substantial equivalence decision.[3] This includes non-conformance with Section 206 requirements. Because 510(k) review of the labeling is confined to the determination of substantial equivalence and not to conformance with other statutory requirements, including 21 CFR Parts 801 or 809, scientific reviewers are not responsible for assessing the labeling provided in 510(k)s for compliance with Section 206 requirements. If during the course of a 510(k) review, it is noted that there is a question

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[2] Any changes other than simply converting paper labeling to an electronic form may require the submission of a PMA supplement or a new 510(k). PMA and 510(k) holders should apply the same criteria that are currently used for determining the need to submit a premarket submission for labeling modifications that impact the design of the device, or otherwise significantly affect the safety and effectiveness of the device.

[3] Section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act states that FDA may not withhold a 510(k) determination because of a failure to comply with any provision of the act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing practices (other than a finding that there is a substantial likelihood that the failure to comply will potentially present a serious risk to health).

regarding the eligibility of a particular device for having labeling strictly in electronic form, reviewers should notify the Office of Compliance (OC) about this concern and refer submitters to OC to discuss the applicability of Section 502(f) to that particular device. However, the reviewers should not stop the review of the 510(k).

Review Procedures for Premarket Submissions

While most conversions of paper labeling to electronic labeling for eligible devices will occur without ODE/OIVD involvement, new devices, including existing devices having undergone significant modification, will continue to be the subject of premarket submissions coming to ODE/OIVD for review. Manufacturers of these devices who intend to provide labeling to users strictly in an electronic form are being encouraged to provide proposed labeling for their devices to ODE/OIVD in the same form that it will be provided to health care facilities. Therefore, submissions may include labeling in an electronic format (e.g., CD ROM) or refer to the device manufacturer's website for the labeling. Whatever format is used, applicants and reviewers should consult existing guidance that applies to all electronic submissions.[4] In addition, ODE/OIVD expects the administrative record for each clearance or approval to meet established Agency standards and clearly capture any labeling that was the subject of review.

Submissions referencing the Internet for labeling will likely be limited to: (1) situations where the device that is subject of the submission is available in the international marketplace and the proposed U.S. labeling does not differ and (2) instances where FDA is provided an identification code that permits access to electronic labeling at the firm's website for review purposes only. For applications referencing a website, a paper copy of the labeling must be included in the application so that there is a permanent record of the labeling. ODE/OIVD reviewers may review the labeling provided in the application or accessed via the referenced website, whichever is more convenient. Because the labeling on the Internet could change at any time, the application must also include a statement that the labeling on the website is identical to that contained in the submission. Finally, the administrative record should reflect the location of the labeling that is the subject of the review.

In instances where the ODE/OIVD review results in labeling changes, the submission must be amended to reflect all agreed upon changes. This means that the submitter must provide an updated paper copy of the revised labeling that reflects the agreed upon changes. When labeling changes are necessary and the labeling was accessed via a website, the website may be immediately updated and subsequently reviewed. Regardless of whether the website is immediately updated for review, the submission must be amended to contain a paper copy of the revised labeling before ODE/OIVD provides a final decision on the submission.

Please note that we will update the review procedures outlined above as the agency's information technology capabilities advance and we review our experience with electronic labeling. A day may arrive when we receive premarket submissions in electronic form and paper copies are no longer

[4] Refer to http://www.fda.gov/cdrh/elecsub.html for detailed information regarding electronic submissions submitted to ODE/OIVD. Specifically, until FDA is equipped to review electronic submissions without an accompanying paper copy, all premarket applications will need to include a paper copy of the labeling.

necessary. Until that time, we need to ensure that the administrative record for all of our decisions contains a paper copy of all relevant labeling that reflects any modifications that resulted from our review.

Effective date: This memorandum is effective immediately.

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