STERILMED, INC.
Setting the Gold Standard
in Medical Device Reprocessing

ISO 9001/13485

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BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch
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CITIZEN PETITION

SterilMed, Inc. (SterilMed)[1] respectfully submits this petition under Section 515 of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to modify the August 14, 2001, deadline for submission and approval of a premarket approval application (PMA) as required by the August 14, 2000, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Guidance). SterilMed respectfully requests that the deadline for the submission of a completed PMA be modified to extend until August 14, 2002. This should be a submission deadline, and should not include the time necessary for the Food and Drug Administration (FDA) to review and respond to the application. Due to the urgency of this petition, SterilMed will assume the petition is denied if FDA has not replied by August 14, 2001.

A. Action Requested

SterilMed requests that FDA modify the August 14, 2001, deadline regarding submission and approval of a PMA. Currently, the Guidance sets an August 14, 2001, timeframe. SterilMed requests that the timeframe be modified to allow submission of a completed PMA until August 14, 2002. SterilMed further requests that FDA allow continued marketing during FDA review of the completed PMA.

B. Statement of Grounds

1. FDA's August 14, 2001, deadline is unreasonably short and should be lengthened.

A request that a company submit and obtain FDA approval of a PMA within 12 months is, in a word, absurd. The time necessary to: 1) develop the basic requirements for a PMA; 2) develop and conduct the necessary non-clinical tests; 3) develop the clinical protocol; 4) identify and enroll

[1] SterilMed is a third-party reprocessor of medical devices labeled for single use, headquartered in Minneapolis, Minnesota.

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clinical sites and investigators; 5) obtain Institutional Review Board (IRB) approval; 6) locate, enroll, and obtain informed consent from suitable subjects; 7) conduct the clinical study; 8) conduct the necessary patient follow-up; 9) obtain and analyze the results of the clinical study; and 10) draft, revise, finalize, and submit the PMA is usually 12 to 24 months, or longer. This is especially true when, as here, the companies required to submit the PMA have never had to do so in the past. The submission of a PMA was a brand new requirement for the devices in question – reprocessed ablation catheters – which have been safely reprocessed for over a decade. Twenty-four months for completion and submission of a PMA under these circumstances is eminently reasonable.

The 12-month timeframe is dramatically shorter than the timeframes that historically have been permitted for similarly situated entities. For example, in 1994, when FDA determined that software products used by blood establishments to manage donor information were subject to regulation as medical devices, the agency initially provided an entire year for manufacturers to submit PMAs or 510(k)s, and the agency subsequently extended the deadline for another year.[2]

There are numerous other instances where once FDA determined that a 510(k) or PMA was necessary for a "type" of device currently on the market, the agency allowed companies from 12 months to several years to make the submission. In these instances, as well as in similar instances related to drug approvals, none of the manufacturers was held hostage to FDA approving the product in a pre-determined timeframe. It is also interesting to note that when Congress enacted the Medical Device Amendments of 1976, manufacturers of pre-amendment Class III devices were allowed a minimum of 30 months to submit a PMA. 21 U.S.C. § 351(f)(2).

In contrast to all of these examples, the Guidance requires reprocessors to submit and obtain approval of these PMAs within 12 months – by August 14, 2001. As detailed above, this is patently impossible, though SterilMed has made every good faith effort to meet FDA's timeframes.

If there were evidence that protection of the public health warranted requiring such a compressed timeframe, SterilMed would support FDA's August 14, 2001 deadline. However, the facts clearly show that no such public health concern exists. Indeed, FDA itself acknowledges that it has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[3]

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[2] See 59 Fed. Reg. 44, 991 (Aug. 31, 1994); 60 Fed. Reg. 51, 802 (Oct. 3, 1995).

[3] See attached Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to the Medical Device Manufacturers Association (October 6, 1999) (Attachment A).

In fact, SterilMed is concerned that the public health may well be harmed if FDA maintains the August 14, 2001 deadline. Indeed, as Johns Hopkins Hospital observed, access to reprocessed ablation catheters helps physicians provide better care to patients:

> An additional benefit of this interaction is the improved patient care from a level of comfort provided the physician who can use a variety of catheter designs and shapes without incurring the guilty feeling that he/she has dramatically increased the cost to the patient.[4]

Confronted with an impossibly short amount of time for submitting and receiving PMA approval, SterilMed will be forced off the market -- as will the other third-party reprocessors of ablation catheters who have not gained FDA approval.[5] The draconian timeframes required under the Guidance have already forced hospitals to cease reprocessing devices that require PMAs. Therefore, beginning August 15, these important devices will no longer be available to U.S. hospitals.

2. FDA review and approval time should not be included in the timeframe.

In addition to the above objections to the August 14 deadline, SterilMed strongly objects to the notion that its ability to market should be dependent upon FDA approval within a predetermined timeframe. SterilMed advocates that any modification of the timeframe should relate to a submission deadline that does not include FDA review time.

Because of agency resource constraints, delays in reviewing and responding to PMAs are common, and, given that FDA reviewers have no experience with submissions for reprocessed devices, there is likely to be more delay than usual. In proposing to penalize an industry because of FDA's failure to approve or deny a submission within a predetermined timeframe, the agency has, once again, dramatically departed from prior practice.

3. Conclusion.

The approach laid out in the Guidance is unprecedented. Proponents of additional regulatory burdens for reprocessors argued that original equipment manufacturers and reprocessors should have

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[4] See attached letter from Johns Hopkins Hospital (Attachment B); see also Comments to Docket No. 00D-0053 regarding FDA's draft guidance documents, submitted by the Association of Medical Device Reprocessors (April 11, 2000) (Attachment C).

[5] It is SterilMed's understanding that no other reprocessors will have attained PMA approval by August 14.

a "level playing field." By providing reprocessors of Class III devices 12 months to prepare, submit, and receive FDA approval, FDA has created a "playing field" where no reprocessor has a fair shot at "winning." When reprocessing loses, patients and hospitals lose too. SterilMed has worked in good faith to meet the Guidance requirements, though SterilMed suspected on August 14, 2000, that strict adherence to these timeframes would be impossible.

Objections to the timeframes through its trade association, the Association of Medical Device Reprocessors (AMDR), and in numerous meetings and phone calls with the agency, have proven fruitless.[6] This Citizen Petition now asks FDA to modify the August 14, 2001, deadline and to extend the time permitted for submission of a PMA until August 14, 2002. The Citizen Petition further requests that FDA continue to allow the marketing of the products covered by the PMA until FDA makes a final decision on the PMA.

C. Environmental Impact

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31.

D. Economic Report

SterilMed will submit an economic analysis upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petitioner relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Craig Patnode pp

Craig Patnode
Chief Executive Officer
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cc: Dr. David Feigal
Dr. Larry Kessler
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[6] For a more detailed review of these issues, see AMDR Comments (Attachment C).