ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

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DIRECT DIAL
(202) 737-7554

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BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket No. 99N-449 1

Dear Sir or Madam:

The Association of Disposable Device Manufacturers (ADDM) respectfully submits this alternative strategy as a comment in response to the Notice entitled, "FDA's Proposed Strategy on Reuse of Single Use Devices." 64 Fed. Reg. 59782 (Nov. 3, 1999). On November 3, the U.S. Food and Drug Administration (FDA) published its proposed strategy on the regulation of reprocessed single use medical devices (the FDA Strategy). ADDM has been actively involved in bringing this important patient safety issue to the forefront of the Center for Devices and Radiological Health (CDRH) agenda and continues to pursue the appropriate regulation of reprocessed single use devices. As part of its formal comments on the FDA Strategy, ADDM is submitting an alternative strategy for the regulation of reprocessed disposable devices (the ADDM Proposal). Unlike the FDA Strategy, the ADDM Proposal is based on applicable provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act) rather than on selective non-enforcement against manufacturing activity that violates the FDC Act. The details of the ADDM Proposal are provided in the attached draft Federal Register Notice. A general description is provided below.

The Historical ADDM Position and the FDA Strategy

To date, ADDM has consistently called for enforcement of all applicable requirements of the FDC Act, including the premarket submission requirements, against reprocessors of disposable medical devices. FDA has acknowledged that the FDC Act requires submission of 5 1 O(k)s and premarket approval applications (PMAs) for these

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◆P.O. Box 344, 1429 G. Street, N.W., Washington, D.C. 20005 Telephone: 202-737-7554, Fax: 202-737-9329◆

99N-4491

devices, but has declined to enforce this requirement. In addressing FDA's stated concerns regarding resources and the potential impact of immediate enforcement of the premarket submission requirements on hospitals, ADDM has indicated its willingness to work out a staggered implementation plan based on device classification. This implementation plan, however, must be streamlined to avoid unnecessary patient exposure to unsafe reprocessed disposable devices.

Rather than require premarket submissions for all reprocessed disposable devices that do not qualify for an exemption, the FDA Strategy would only enforce the 5 1 O(k) and PMA requirements for some reprocessed devices which FDA deems to be "high risk" (under criteria that the agency has not yet announced) and would delay implementation of even this limited plan. FDA has indicated that the new classification scheme would require premarket submissions for only a small subset of reprocessed devices, and would continue to use enforcement discretion as to the others. In addition to the patient safety issues raised by the FDA Strategy, this approach would perpetuate the confusion surrounding Medicare reimbursement for reprocessed single use devices. The Health Care Financing Administration (HCFA) has publicly concluded that Medicare will not reimburse for unlawfully marketed devices, even if the FDA utilizes enforcement discretion to overlook the unlawfulness. The FDA Strategy also has other serious flaws which will be set out in length in future detailed comments.

By proposing an alternative strategy which protects patients via premarket submissions while ensuring that all reprocessed single use devices are lawfully marketed, even during the implementation phase, the ADDM Proposal complies with FDA's Congressional mandate, minimizes risks to patients, appropriately allocates Agency resources and resolves Medicare reimbursement issues.

The ADDM Pronosal

ADDM continues to believe that data-based premarket submissions for reprocessed single use devices are essential to patient protection. Nonetheless, due to years of FDA regulatory discretion, some hospitals have come to rely on the availability of such devices even in the absence of FDA approval establishing safety or effectiveness of the device. ADDM therefore recognizes that an abrupt removal of all reprocessed disposable devices while these submissions are being prepared and reviewed could disrupt the health care system. To address this concern, the ADDM Proposal calls for limited temporary exemptions from premarket submission requirements for Class I and Class 11 reprocessed single use devices. Due to the potential patient safety risk, Class III single use devices would not be afforded a grace period – that is, reprocessed Class III devices could be marketed only in accordance with an approved PMA. At the end of the temporary

exemption period for Class I and Class II devices, the ADDM Proposal calls for premarket submissions for all reprocessed single use devices. As is true for new devices, however, a single use device reprocessor could submit data to FDA in support of a petition for permanent exemption of a device from the premarket requirements. The core components of the ADDM Proposal then are 1) lawful temporary exemptions for reprocessed Class I and Class II single use devices, 2) data-based permanent exemption petitions for low risk reprocessed single use devices and 3) premarket submissions for all other devices.

The temporary exemptions would result in a staggered grace period for reprocessed Class I and II single use devices. Rather than rooting this grace period in FDA's extralegal assertion of enforcement discretion, the ADDM Proposal utilizes the provisions of the FDC Act to immediately grant all reprocessed Class I and II disposable devices a temporary exemption from the premarket notification requirements. In light of the safety risks presented by reprocessed single use devices, the length of this grace period cannot be justified unless it is carefully limited to allow the minimum time necessary for preparation and review of premarket submission for devices which can be demonstrated to be safe the effective. Longer exemptions would only result in unjustifiably increased patient risk or injury. The temporary exemption would be based on the device's original class and would sunset either six or nine months after publication of the policy in the Federal Register. Once the temporary exemption sunsets, devices in that class could lawfully be reprocessed only under a cleared 5 1 O(k) or petition-based permanent exemption.

Under the ADDM Proposal, reprocessed Class I and II single use devices would be required to comply with the 5 10(k) premarket notification requirements. However, as with new devices, reprocessors could opt to petition FDA for data-based exemptions from the premarket requirements under the FDC Act. In this way, the ADDM Proposal allows for exemption of low risk reprocessed single use devices under the exemption mechanism established by Congress and implemented by FDA, properly balancing patient safety and agency resource concerns.

Strategy Comnarison

The ADDM Proposal addresses the concerns of all stakeholders by complying with the FDC Act, protecting patients through data review, allowing exemptions for low risk devices, properly allocating agency resources through phased implementation and allowing Medicare reimbursement. It is designed to uphold the fundamental FDC Act requirement that devices obtain approval, rather than ignore this statutory directive. In addition, by utilizing the existing classification, premarket review and exemption procedures, the ADDM Proposal remains faithful to the scientific standards that have been developed by CDRH over the last 26 years. These standards have protected patients and provided for the

safe introduction of new technologies that have improved the lives of millions. As such, ADDM believes that implementation of its proposal would represent sound FDA policy and best protect public health.

Sincerely,

Josephine M. Torrente

JMT/dmb

cc: Stephen Brobeck
Joan Claybrook
Marcia Crosse
Peter Derschang
John Fielder, Ph.D.
Linda Golodner
David Hennage, Ph.D.
Jeff Kang, M.D.
Larry Kessler, Sc.D.
Gene Kimmelman
Karen Laing, RN
Christopher Lavanchy
Dirksen Lehman
John Manthei
Abbey Meyers
Ann Marie Murphy
Cynthia Pearson
Joseph Perkins
Stacey Rampy
Mary Beth Savary-Taylor
Alan Slobodin
Jennifer Thomas
Edward Truschke
Eleanor Vogt

ATTACHMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No.]_____

Medical Devices; Temporary Exemptions From Premarket Notification; Reprocessed Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish procedures for requiring device reprocessors to comply with the premarket notification process prior to marketing or distributing reprocessed single-use medical devices and to enable orderly implementation of this requirement. These amendments are being made to implement existing requirements under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is publishing these amendments in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register,** FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws this final rule.

DATES: This rule is effective [60 days after publication]. Submit written comments on or before [30 days after publication].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. l-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: _____

SUPPLEMENTARY INFORMATION:

I. Background

The origins of devices designed for only one use (referred to as "single-use devices") can be traced back to the 1948 invention of the first plastic, nonbreakable container for the storage of blood components. Prior to this time most medical devices were "reusable," that is, they were intended to be used and reprocessed. The advantages of single-use devices were readily apparent: they prevented cross-infection, saved space, were lightweight, and virtually eliminated breakage.

Design and material considerations vary greatly between single-use and reusable devices. Reusable devices must be designed to allow for thorough cleaning and sterilization. As a result, most reusable devices are easily disassembled, have smooth surfaces, and are made of durable materials such as stainless steel. By comparison, single-use devices are designed for optimal single use performance, rather than easy cleaning, and may be seriously compromised or destroyed by common reprocessing methods. Single-use devices may contain many areas that are difficult to access, such as long, narrow, lumens, acute angles, crevices, coils, and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas can create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, respiratory secretions, and gastric mucin.

The practice of reusing single-use devices was initially presumed to be as safe as the use of reusable devices. A number of early incidents challenged the medical community's general presumption that reprocessing is safe. In the late 1950s, a New Jersey dentist reused hypodermic needles that were inadequately sterilized, and unwittingly injected nine patients with hepatitis. All nine patients died as a result. In England in the 1970s, the reprocessing of disposable oxygenators that were intended for use in heart bypass operations led to several fatal immune reactions that were linked to pyrogens not removed by the cleaning process. By the late 1970s and early 1980s, even more complex plastic devices were being developed, and Original Equipment Manufacturers (OEMs), increasingly aware of the potential for patient injury due to improper reuse and the need for different design characteristics in single use devices, began to label an increasing number of devices as "single use only."

In recent years, with the advent of managed care, the practice of reprocessing single-use devices expanded as a cost-saving measure. Since then, more complex products (e.g., balloon angioplasty catheters and cardiac catheters) have begun to be reprocessed and an industry of third-party reprocessors has emerged. The commercialization of this practice and the increasingly complex types of single-use devices that are being subjected to reprocessing has intensified concern regarding patient safety and the equitable regulation of OEMs and reprocessing firms.

Evidence of increased patient risk due to reuse of single use devices has mounted over the past several years. FDA's MedWatch system, while not designed to capture adverse events caused by reprocessing, does suggest that serious problems exist with reprocessed disposable devices. In addition, reports from numerous scientific studies submitted to FDA by OEMs and hospitals indicate that many reprocessed disposable devices are not sufficiently cleaned or sterilized and do not retain key functional characteristics. The reports have been substantiated by data developed at FDA on hundreds of reprocessed single use devices. These data demonstrate the post-reprocessing differences between seemingly similar devices and the need for device-by-device evaluation.

Establishments that engage in reprocessing of single-use devices for reuse are subject to all requirements of the Act and FDA's implementing regulations, including: registration and listing (2 1 CFR Part 807); premarket notification and approval requirements (2 1 CFR Parts 807 and 8 14); submission of adverse event reports under the Medical Device Reporting regulation (2 1 CFR Part 803); manufacturing requirements under the Quality Systems regulation (2 1 CFR Part 820); Labeling requirements (2 1 CFR Part 801); Medical Device Tracking (21 CFR Part 821); and Medical Device Corrections and Removals (2 1 CFR Part 806). However, FDA has, in the exercise of its enforcement discretion, not taken action against third-party reprocessors for noncompliance with premarket notification requirements. The agency signaled that this discretionary non-enforcement was under review in a July 9, 1999 letter to counsel for the Association of Medical Device Reprocessors. In that letter, FDA concluded that it had not reviewed sufficient data to make a determination regarding the safety of the continued reprocessing of single-use devices. The agency further stated that:

> Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. However, FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements until a new FDA reprocessing position is adopted.

FDA's discretionary non-enforcement has had an impact on the Medicare coverage of reprocessed single-use devices. In a September 8, 1999 letter to counsel for the Association of Disposable Device Manufacturers, the Health Care Financing Administration (HCFA) announced that Medicare would reimburse for reprocessed single-use devices only if reprocessing is lawful under the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations.

FDA has determined that there is a pressing and immediate need to ensure that only safe and effective reprocessed single-use devices remain available for use in

patients. The agency also believes that, due to years of enforcement discretion, reprocessed single use devices are routinely used by some hospitals, and that these hospitals have come to rely upon the availability of reprocessed single use devices. Thus, an immediate call for premarket submissions could result in a reduction in the pool of devices that may be used for treatment while the submissions are being prepared and reviewed.

Conversely, there is a significant risk in allowing these devices to remain on the market in the absence of data that demonstrates the reprocessed devices are at least as safe and effective as the single-use devices on which they are based. In general, FDA expects that risks associated with reprocessed single use devices will be at least as serious as those associated with the corresponding, new single-use devices. Thus, the agency expects that, in general, the risk of reprocessing a Class III single-use devices generally will be much greater than the risks of reprocessing Class I single-use devices.

With this final rule, FDA is announcing that it will no longer adhere to its former position of discretionary non-enforcement with respect to reprocessed single-use devices. Due to the serious risk to patient safety posed by the reuse of Class III disposable devices, as of the effective date of this final rule, FDA will take enforcement action against reprocessed Class III single-use devices that are not the subject of an approved PMA. The agency is also announcing the temporary exemption of reprocessed Class I and II single-use devices as of 60 days after the date of publication of this final rule as Class I Exempt and Class II Exempt, respectively to allow for orderly implementation of the premarket submission requirement

At the end of the temporary exemption, all reprocessed Class I and Class II devices will be regulated as non-exempt Class I and II devices. The exemption for reprocessed Class II devices will expire 180 days after the date of publication of this final rule, and the exemption for reprocessed Class I devices will expire 270 days after the date of publication. Once these exemptions lapse, the reprocessed single-use devices must either be cleared under the premarket notification process or permanently exempted from premarket notification pursuant to the petition process of section 513(f)(3) (21 U.S.C. 360c(f)(3)).

This staggered implementation of the premarket notification requirements will allow FDA to adhere to a risk-based mechanism of regulation while minimizing disruption that would result from the sudden unavailability of reprocessed devices. Additionally, this approach will allow FDA to bring reprocessed single-use devices into full compliance with the Act without unnecessarily straining the agency's administrative resources.

II. Final Rule

The Act prohibits the distribution of new devices that are not approved under a premarket approval application (PMA), cleared under a 5 1 O(k) premarket notification (510(k)), or subject to an exemption from premarket review. A new 5 10(k) clearance or exemption is also required when a device's intended use is significantly changed, such as a change from single use to reusable. FDA routinely requires a new 5 1 O(k) when an OEM seeks to change the labeling of a device from single use to reusable. The FDC Act and its implementing regulations similarly require reprocessors of single-use devices to obtain FDA clearance of a 5 1 O(k) or obtain an exemption prior to distribution of their devices.

With respect to establishing the exemption for reprocessed Class II single-use devices, section 5 1 O(m)(2) of the Act provides that FDA may exempt a device on its own initiative or upon petition of an interested person. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination.

In the short term, FDA believes that the impact to the healthcare system that would result from the immediate elimination of reprocessed Class II single-use devices should be minimized by exempting these devices from the premarket notification requirements for a period of time sufficient to allow for the preparation and review of 510(k) submissions and exemption petitions. Accordingly, FDA believes that, for the proposed 1 80-day exemption period, 5 1 O(k)s will not be necessary for these devices under the standards set forth in §5 1 O(m)(2).

Under section 510(*l*) of the Act (21 U.S.C. 360(*l*)), a Class I devices is presumed to be exempt from the 5 10(k) premarket notification requirement unless the device is intended for a use that is of "substantial importance in preventing impairment of human health" or that presents a "potential unreasonable risk of illness or injury." As with reprocessed Class II single-use devices, FDA believes that the impact on the healthcare system which would result from the immediate elimination of reprocessed Class I single-use devices should be minimized by exempting these devices from the premarket notification requirements for a period of time sufficient to allow for the preparation of 5 1 O(k) submissions and exemption petitions and their review by the agency. Accordingly, FDA believes that, for the proposed 270-day exemption period, 5 10(k)s will not be necessary for reprocessed Class I single-use devices under the standards set forth in §510(*l*).

III. Rulemaking Action

In the **Federal Register** of November 2 1, 1997, FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial

amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend existing part 800. The companion proposed rule and the direct final rule are substantively identical. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of a significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments to the companion proposed rule will be considered as comments regarding the direct final rule.

FDA has provided a comment period on the direct final rule of 30 days after the date of publication of these documents. If the agency receives a significant adverse comment, FDA intends to withdraw this final rule by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the proposed rule in developing a final rule in accordance with usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation notice within 30 days after the comment period ends confirming that the direct final rule will go into effect on [60 days after publication].

IV. Environmental Impact

V. Analysis of Impacts

VI. Comments

Interested persons may, on or before [30 days after publication], submit to the Dockets Management Branch (address above) written comments regarding this direct final rule. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the companion proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and this direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 800

Under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 800 is amended as follows:

PART 800 – GENERAL

1. The authority citation for 2 1 CFR part 800 continues to read as follows:

Authority: **21** U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361,362, 371.

2. Part 800 is amended by adding:

§ 800.__ Temporary Exemptions for Reprocessed Single Use Devices.

(a) Reprocessed Class I medical devices labeled as disposable, or otherwise labeled for single use only, are exempt from the premarket notification requirements of subpart E of part 807 of this chapter until [270 days after publication of the Direct to Final Rule]. After such date, these devices shall be subject to all applicable requirements for Class I Reserved medical devices, including the need for clearance of a premarket notification pursuant to the requirements of subpart E of part 807 of this chapter.

(b) Reprocessed Class II medical devices labeled as disposable, or otherwise intended for single use only, are exempt from the premarket notification requirements of

subpart E of part 807 of this chapter until [180 days after publication of the Direct to Final Rule]. After such date, these devices shall be subject to all applicable requirements for Class II Non-Exempt medical devices, including the need for clearance of a premarket notification pursuant to the requirements of subpart E of part 807 of this chapter.

Dated: _____