DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Larry R. Pilot
McKenna & Cuneo, L.L.P.
1900 K. Street, N.W.
Washington, DC 20006

Docket No. 99P-1516

Dear Mr. Pilot:

This is in response to your petition for reconsideration dated October 21, 1999 and your letter of the same date concerning the appropriate person to sign a petition response. In your petition, you requested that the Food and Drug Administration (FDA) reconsider its denial of your petition on behalf of the Medical Device Manufacturer's Association dated May 20, 1999. In a letter dated June 23, 2000, you requested that FDA suspend review and action on your petition for a period of 180 days. Since 180 days have passed, we have resumed action and are denying your petition for the reasons stated below.

A. Delegation of Authority to Respond to Citizen Petitions

In your letter of October 21, 1999, you state that the Commissioner of FDA has not delegated to the Director of the Center for Devices and Radiological Health (CDRH) the authority to respond to a citizen petition submitted under Title 21 of the Code of Federal Regulations 10.30 (21 CFR 10.30)

The Commissioner redelegated the authority to respond to a citizen petition under §10.30 to the Deputy Commissioner for Policy under 21 CFR 5.20(f)(2)(ii). On November 18, 1996, William B. Schultz, then Deputy Commissioner for Policy, redelegated to the Director and Deputy Director of CDRH and the Director of the Office of Health and Industry Programs, CDRH, the authority to issue responses to citizen petitions.

B. Response to Original Citizen Petition.

In your petition of May 20, 1999, you requested FDA to issue a proposed regulation identifying reprocessed single-use devices as banned devices and declaring such proposed regulation to be effective upon its publication in the *Federal Register*.

99P-1516 PDN 2

The criteria for banning a device are set out in section 516 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360f) as follows:

> **SEC. 516. [360f]** (a) Whenever the Secretary finds, on the basis of all available data and information, that -
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> (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and (2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period; he may initiate a proceeding to promulgate a regulation to make such device a banned device.
>
> Special Effective Date
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> (b) The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if
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> (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

On October 6, 1999, FDA denied your petition. FDA stated that there is no clear evidence of adverse patient outcomes associated with the reuse of a single-use device from any source. Therefore, FDA determined that it could not conclude that reprocessing presents an "unreasonable and substantial risk of illness or injury." FDA further determined that it could not conclude that there was a "substantial deception," because it would be difficult to establish whether deception with regard to reprocessed products has occurred and who was the target of that deception. Finally, FDA concluded that, even if there were a substantial deception, banning would not be the appropriate response, because there is no evidence of danger to individual health from reprocessing of single-use devices.

C. Petition for Reconsideration

In your petition for reconsideration, you object to FDA's determination that it cannot conclude that there is an "unreasonable and substantial risk of illness or injury," because FDA was unable to find clear evidence of adverse patient outcomes. You further argue that FDA incorrectly concluded that there was not a substantial deception. You state that, according to the act and FDA's regulations (21 CFR 895), there is no need for actual proof of deception or of injury to an individual.

Under § 10.33(d) of FDA's administrative practices and procedures regulations (21 CFR 10.33(d)), before granting a petition for reconsideration, FDA must determine that all of the following are true:

1. The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

2. The petitioner's position is not frivolous and is being pursued in good faith.

3. The petitioner has demonstrated sound public policy grounds supporting reconsideration.

4. Reconsideration is not outweighed by public health or other public interests.

FDA believes that you have not met this burden. You have not demonstrated that FDA did not adequately consider the views and information contained in your May 21, 1999 petition. Nor have you shown that there are sound public policy grounds supporting reconsideration.

FDA has adequately considered the views and information in your previous petition.

In your petition for reconsideration, you argue that FDA applied incorrect criteria in determining not to ban these devices. You state that there is no need to find any adverse reports or actual proof of deception before banning a product. FDA agrees with the last statement.

However, we nonetheless affirm our position. Based on all the evidence, including all available evidence of patient harm and deception, we have concluded that the degree of risk and/or deception does not rise to the level of substantial risk or deception that would warrant banning these devices.

In accordance with the legislative history and FDA's regulations, to ban a device, FDA must determine that the risk of illness or injury or the deception is "important, material, or significant in relation to the benefit to the public health from its continued marketing." 21 CFR 895.21(a)(1)). FDA cannot make such a conclusion in this case.

We recognize that there are risks to patients from the reuse of some devices, and that patients may be unaware that products are reused, as you describe in your petition. These are the same factors, however, which FDA previously considered in denying your original petition. Your petition, therefore, does not satisfy the requirement, under 21 CFR 10.33(d), that you demonstrate that relevant information or views contained in the administrative record were not previously or adequately considered.

There are no sound public policy grounds supporting reconsideration

Your petition does not demonstrate sound public policy grounds for supporting reconsideration, as required by 21 CFR 10.33(d). As stated above, we do not find the requisite degree of risk or deception that would warrant the action of banning these devices to protect the public health.

D. Other Actions Taken by FDA concerning Reuse

Although FDA is denying your petition, we would like to point out that, since our response to your original petition, FDA has taken a number of steps that further reduce the degree of risk posed by the reuse of single use devices. FDA believes these steps represent a sound public policy approach to addressing risks posed by these products.

On December 14, 1999, FDA held an open public meeting to provide interested parties an opportunity to comment on FDA's proposed strategy on reuse of single-use devices. On February 11, 2000, FDA announced the availability of two draft guidance documents addressing enforcement priorities for single-use devices reprocessed by third parties and hospitals. FDA invited interested persons to comment on these guidance documents by April 11, 2000. FDA received over 40 comments, including one from MDMA. FDA reviewed these comments and issued a single revised guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (enclosed).

The guidance creates a level playing field for original equipment manufacturers, third party reprocessors, and hospitals that reprocess single use devices. FDA intends to enforce existing regulatory requirements, including premarket requirements and adverse event reports, against

hospitals and third parties who reprocess single use devices. These requirements are the same as those applied to original equipment manufacturers to help ensure safety and effectiveness. Accordingly, there is no public policy reason to ban these devices when they are subject to the same regulatory requirements as any other devices on the market.

E. Conclusion

For the reasons stated above, FDA is denying your petition for reconsideration.

We will continue to evaluate the effectiveness of the steps that we have taken to address concerns about reuse of single use devices and will take additional action, if necessary.

If you have any questions about this response, please call Larry Spears of our Office of Compliance at (301) 594-4646.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and
Radiological Health