

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier N. Hawkins

[Docket No. 00D-0053]

Determining Hospital Procedures for Opened-But-Unused, Single-Use Medical Devices; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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SUMMARY: The Food and Drug Administration (FDA) is providing an opportunity for interested persons to submit comments about current practices with respect to opened-but-unused, single-use medical devices. FDA is publishing this notice in order to gather informed comment from individuals, professional organizations, original equipment manufacturers, reprocessors, and hospitals as it examines its policy with respect to opened-but-unused, single-use medical devices.

DATES: Submit written comments by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Larry Spears, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4692.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2000 (65 FR 49583), FDA published a guidance entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." The guidance defined "opened-but-unused" devices as:

Single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not been used on a patient, that is, they have not been in contact with blood or bodily fluids.

The guidance did not apply the agency's enforcement priorities for reprocessed devices to opened-but-unused, single-use medical devices reprocessed in hospitals. The guidance did state, however, that the agency would examine its policy with respect to opened-but-unused, single-use medical devices. In doing so, FDA is soliciting information about current practices regarding this issue. A copy of the guidance is available on FDA's Web site at <http://www.fda.gov/cdrh/reuse/1168.html>.

FDA is interested in comments related to: (1) Whether or not hospitals have a written policy or procedure for handling sterile, single-use medical devices that are opened, for whatever reason, but are unused; (2) how hospitals determine if a single-use medical device that has been opened but unused is contaminated; and (3) what types of single-use medical devices are resterilized because they are opened but unused.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments or information regarding this issue by *[insert date 90 days after date of publication in the Federal Register]*. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/19/02
August 19, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins