



Mary Ellen Lynch
Director of Regulatory Affairs

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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, Md 20857

SUBJECT: Medical Devices; Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Rememberers of Medical; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information. 62 Federal Register 246, December 23, 1997.

To Docket No. 97N-0477:

Browning-Ferris Industries, Inc. submits the following comments to the Food and Drug Administration (FDA) concerning regulatory requirements relating to the remarketing of used medical devices.

Browning-Ferris Industries, Inc. (BFI) is one of the largest publicly held companies whose subsidiaries and affiliates collect, process for recycling, transport, and dispose of a wide range of commercial, industrial, medical and residential solid wastes. BFI subsidiaries also are involved in the operation of resource recovery facilities.

BFI owns or operates 29 regional medical waste treatment sites, serving more than 154,000 health care customers. Our health care customers include hospitals, other health care facilities, health care providers in private and group practice, and other individuals who use medical sharps in a home or business setting. BFI provides medical and veterinary sharps (e.g., needles and syringes) collection and disposal service to customers through route collection service as well as through a mail-in service authorized by the U.S. Postal Service (USPS) pursuant to the Domestic Mail Manual (DMM) C023.10.5h and 10.5j.

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BFI urges FDA to proceed with rulemaking that will establish strict regulatory requirements for the remarketing of used medical devices, including used sharps disposal containers, and persons who market and refurbish reusable sharps disposal containers. From our experience as the largest provider of medical waste collection and disposal services in the world, BFI believes that mandatory registration, listing and current good manufacturing practice (CGMP) regulations should be applied to refurbishers or servicers of reusable sharps disposal containers.

The Food and Drug Administration regulates sharps disposal containers as a class II medical device subject to special controls and performance standards intended to ensure their safe and effective use. [21 CFR 860.3]

In addition, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor has established minimum design performance elements for sharps disposal containers. [29 CFR 1910.1030(d)(4)(iii)(A)] The OSHA standard includes the requirement that "[R]eusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury."

According to the most recent evaluation of sharps disposal containers conducted by the National Institute for Occupational Safety and Health (NIOSH), a sister agency of the FDA within the Department of Health and Human Services, "the correct and consistent use of rigid sharps disposal containers in the health care environment has been demonstrated to reduce the number of needle stick injuries." [National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services, DHHS Publication No. 97-111, January, 1998.] FDA regulations are necessary to establish manufacturing and safety performance criteria for reusable sharps disposal containers that will apply over the life of the device and to ensure the reusable containers remain functional during their entire usage.

Health care workers, as well as servicing personnel, including waste collection and processing workers, deserve the same protection from reusable sharps disposal containers that they receive from properly manufactured single use sharps disposal containers.

Reusable sharps disposal container manufacturers and refurbishers/servicers should be subject to regulations that, among other requirements, assure users of the devices and other health care facility patients and workers who come into contact with the devices, as well as device collection and disposal workers, that the reusable containers (1)

comply with the OSHA safety standard, (2) are rendered free of infectious organisms and infectious material each time they are processed and before they are returned to service, and (3) are routinely retired when surface cleaning is no longer effective and/or the materials begin to breakdown.

This is especially critical given the large number of people potentially exposed to bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and other potentially infectious agents and the critical role sharps disposal containers play in reducing that exposure. According to NIOSH,

The primary route of occupational exposure to bloodborne pathogens is accidental percutaneous (through the skin) injury. Health care workers handle sharp devices and equipment such as hypodermic and suture needles, intravenous blood collection devices, phlebotomy devices and scalpels. Of the 800,000 needlestick injuries (NSIs) estimated to occur in the hospital setting annually, the greatest number occur to health care workers with the most involvement in direct patient care. Nursing staff and phlebotomists sustain the highest percentage of reported NSIs.

Hospital NSI studies have shown that many of these injuries occur after the device is used and during disposal activities. As many as one third of all sharps injuries have been reported to be related to the disposal process. The factors most often related to sharps injuries include the following:

- o Inadequate design or inappropriate placement of the sharps disposal container...

Important elements of an overall prevention strategy include the following:

- o Engineering controls...

The routine use of rigid sharps disposal containers in the health care environment has been demonstrated to reduce NSIs. [DHHS (NIOSH) Publication No. 97-111, January, 1998.]

While we recognize that FDA is at an early stage in evaluating its policy and developing regulations concerning refurbishers and servicers of medical devices, we urge the Agency not to delay evaluation of current policy and

development of regulations addressing the growing practice of manufacturing and marketing reusable sharps disposal devices. FDA scrutiny of these devices is necessary to avoid unnecessary worker and public exposure to infectious disease.

Please contact me if you have questions about BFI's interest in this FDA regulatory activity or if you would like additional information or have questions about these comments. In addition, please include me in your stakeholder contacts list for this rulemaking.

Sincerely,


Mary Ellen Lynch



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