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2013 OCT 17/CE/DDM

September 19, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Citizen Petition

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to amend 21CFR 804.3(d).

A. Action requested

Request changing the definition of a Distributor in 21CFR 804.3(d) and other locations in 21CFR to assure patient safety in applying QSR requirements to all marketing of any device sold in the United States.

Current Regulations

1) DISTRIBUTOR [§804.3(d)]

A "distributor" is any person, including an importer, who furthers the marketing of a device from the place of original manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the device or the container, wrapper, or labeling of the device or device package.

Requested Change

2) DISTRIBUTOR [§804.3(d)]

A "distributor" is any person, including an importer, who furthers the marketing of a device from the place of the original manufacturer's installation or importation, to any person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the device or the container, wrapper, or labeling of the device or device package.

B. Statement of grounds

Manufacturers are required to track certain devices from their manufacture through the distribution chain when they receive an order from the agency to implement a tracking system for a certain type of device. The purpose of device tracking is to ensure that

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manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices.

Off device master record sales after the initial manufacturer's installation or importation are not tracked through the manufacturer's device master record tracking methods. The intent of the FDA is to assure device safety through tracking devices. Device safety cannot be assured after devices enter into off device master record sales to second and third User by any person.

C. Environmental impact

None

D. Economic impact

None

E. Certification

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

Terry L Tennant

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