May 20, 2015

2015 MAY 21 A

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types – Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 20, 2015), Docket No. FDA-2015-N-0025

Dear Sir/Madam:

We are submitting these comments on the Food and Drug Administration's January 20, 2015 Federal Register notice and draft guidance on Medical Device Accessories, on behalf of a manufacturer, importer, and distributor of medical device components. While we support the FDA's efforts to provide a definition of "accessory" and to establish a classification pathway for new accessory types, we have significant concerns with the proposed definition. As described further below, FDA's proposed new definition of "accessory" would overlap with the current regulatory definition of "component" and would have the effect of reclassifying many device components as accessories, thus subjecting the manufacturers of such components to significant new regulatory burdens. Therefore, we strongly recommend the following:

- FDA should revise its proposed definition of "accessory" to avoid any overlap with the current regulatory definition of "component," and provide guidance on how to determine whether an item is a device component or an accessory.

- FDA should consider the potential regulatory impact of its proposed "accessory" definition on component manufacturers. As part of this analysis, we recommend that FDA assess the economic impact on component manufacturers that would result from any change that may affect the current regulatory definition of "component."

- FDA should ensure that any change that impacts the current regulatory definition of "component" is done via notice-and-comment procedures, consistent with the requirements of the Administrative Procedure Act.

We discuss each of these issues further below.

I. FDA's Proposed Definition of "Accessory" Would Overlap with the Current Regulatory Definition of "Component"

FDA's regulations define a device component as "any raw material, substance, piece, part, software, firmware, labeling, or assembly *which is intended to be included as part of the*

CDRH

finished, packaged, and labeled device."[1] The proposed draft guidance would define a device accessory as: "A device that is intended to *support*, supplement, and/or augment the performance of one or more parent devices."[2] In its draft guidance, FDA states that a device "supports" a parent device "by enabling or facilitating that device to perform according to its intended use."[3] The Agency further states that a rechargeable battery for use with an automated external defibrillator ("AED") constitutes a device accessory because the battery "supports the AED by enabling it to defibrillate."[4] Items such as batteries, however, have traditionally been viewed as components when they are "intended to be included as part of the finished, packaged, and labeled device."[5] Further, we are uncertain how the explanation of "support" in the Medical Device Accessories Draft Guidance helps to differentiate the role of a battery from, for example, a circuit board. Both help the device to perform its intended use. As written, the proposed definition and examples in the Medical Device Accessories Draft Guidance would effectively result in FDA redefining what items would be considered components versus accessories.

This distinction is not mere semantics. Manufacturers of device components are generally exempt from most FDA regulatory requirements, including, for example, registration and listing;[6] 510(k) premarket notification requirements;[7] and good manufacturing practices, as set forth in the Quality System Regulation ("QSR").[8] Device accessories, however, are considered finished devices[9] and, therefore, manufacturers of device accessories must comply with these regulatory requirements. Thus, any restriction in the scope of items regulated as device components, or expansion in the scope of items regulated as device accessories, will have significant regulatory impact for component manufacturers.[10]

---

1 21 C.F.R. § 820.3 (emphasis added).

2 Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types – Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 20, 2015) ("Medical Device Accessories Draft Guidance"), at 4 (emphasis added).

3 *Id.* at 5.

4 *Id.*

5 *See* 21 C.F.R. § 820.3.

6 Under 21 C.F.R. Part 807, component and accessory manufacturers are subject to registration and listing requirements if the components or accessories "are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose." 21 C.F.R. § 807.20(a)(6). While there is a specific exemption for component manufacturers who would otherwise not be required to register under section 807.20(a)(6), there is no such exemption for manufacturers of accessories. 21 C.F.R. § 807.65(a).

7 21 C.F.R. § 807.81 (requiring a premarket notification submission for any manufacturer required to register under Part 807).

8 21 C.F.R. § 820.1 ("This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance.").

9 21 C.F.R. § 820.3 ("*Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.").

10 Component manufacturers would be required to ensure that all of the sites where their "supporting" components are manufactured are registered and have listed these components. Likewise, finished device manufacturers would need to ensure, in particular, that the foreign entities from which they purchase "supporting" components are appropriately registered and listed.

We recommend, therefore, that FDA revise its proposed definition of "accessory" such that it does not overlap with the current regulatory definition of "component." We also recommend that FDA include guidance on how to determine whether an item should be properly regulated as a device component versus a device accessory.

II. FDA Should Consider the Potential Impact on Component Manufacturers

As described above, the proposed new definition of "accessory" could cause items currently regulated as components to become device accessories, which would result in significant new regulatory obligations for the manufacturers of such components. We strongly encourage the FDA to consider the practical and economic impact, as well as the regulatory impact, of the proposed definition on manufacturers of components (as defined under the existing regulations) and on FDA's registration and listing process. As discussed above, we believe that the definition, as currently proposed, potentially could result in foreign and domestic component manufacturers being required to register and list for hundreds, if not thousands, of items that are currently considered device components (and are not subject to registration and listing under existing FDA regulations) as device accessories.[11] Additionally, such manufacturers will need to bring their components into compliance with other FDA regulatory requirements, including premarket submission requirements (as applicable) and QSRs. For these reasons, we respectfully request that FDA consider these impacts before implementing any new definition of "accessory."

III. Implementing a Change That Impacts the Regulatory Definition of "Component" via Guidance Presents Significant Legal Issues

The proposed definition of "accessory" will effectively change the existing regulatory definition of "component" and the regulatory obligations and duties of component manufacturers. These changes would constitute rulemaking promulgated without the notice and comment required by Section 4 of the Administrative Procedure Act ("APA")[12] and, therefore, would be considered unlawful agency action without observance of procedure required by law.[13]

Pursuant to the APA, an administrative agency can only adopt a valid substantive rule through use of APA rulemaking procedures. As noted above, the proposed definition of "accessory" is not simply advisory or interpretive. It will create significant new regulatory duties and obligations for many component manufacturers that are deemed to manufacture components that "support" a finished device, including registration and listing, 510(k) premarket notification requirements, and QSR requirements.[14] Failure of such component manufacturers to comply with these requirements will render their components adulterated and/or misbranded in violation of the Federal Food, Drug, and Cosmetic Act, and will prevent these items from being imported

---

[11] We do not believe that FDA can clarify its definition of "accessory" by simply adding more examples. Use of the word "support" is far too broad and ambiguous to be clarified by examples alone.

[12] 5 U.S.C. § 553.

[13] 5 U.S.C. § 706(2)(D).

[14] Substantive rules "create new law, rights, or duties in what amounts to a legislative act." *Clarry v. United States*, 85 F.3d 1041, 1048 (2d Cir. 1996), *citing White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993).

into or distributed in the U.S. Because the proposed changes will have the force and effect of law, any attempt by FDA to implement or enforce its proposed new definition of a device accessory in the absence of notice-and-comment rulemaking would present significant legal issues under the APA.[15]

* * *

We appreciate this opportunity to comment on the above-referenced January 20, 2015 Federal Register notice and draft guidance.

Respectfully submitted,

M. Elizabeth Bierman

cc: Sugato De, Center for Devices and Radiological Health

[15] 5 U.S.C. § 553(b), (c). *See also Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 93 (D.C. Cir. 1997) (holding that 1995 FDA Guideline announcing regulatory structure for positron emission tomography radiopharmaceuticals was a substantive rule under the APA and, thus, should have been promulgated using notice-and-comment procedures).

00077/064317/0019 MEB

ORIGIN ID:RDVA (202) 739-5229
BECKY ROBINSON
MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVE NW

WASHINGTON, DC 20004
UNITED STATES US

SHIP DATE: 20MAY15
ACTWGT: 0.2 LB
CAD: 0687021/CAFE2807

BILL SENDER

TO **SEE LABEL**
SEE LABEL
SEE LABEL
SEE LABEL
ROCKVILLE MD 20852
(202) 739-5229
REF: 00077-064317-0019-MEB/KWH

FedEx Express

THU - 21 MAY 10:30A
PRIORITY OVERNIGHT

TRK# 0201 **6175 6275 5823**

19 NSFA

20852
MD-US IAD

Part # 154250-354 TRITRA 11/14

1111 Pennsylvania Avenue, NW
Washington, DC 20004

Morgan Lewis
COUNSELORS AT LAW

TO: **VIA FEDERAL EXPRESS**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Envelope