September 22, 2021

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Rm. 1061 (HFA-305)
Rockville, MD 20852

RE: Remanufacturing of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff (Docket No. FDA-2018-N-3741-0044)

Dear Commissioner and Staff:

It is the strong conviction of the 11 undersigned organizations—representing hundreds of companies and hundreds of thousands of workers across multiple industry sectors in the U.S. remanufacturing industry—that the U.S. Food and Drug Administration (FDA) continues to misapply the term ***remanufacturing*** to define an equipment modification process that "significantly changes the finished device's performance or safety specifications, or intended use."[1] While we recognize the regulatory need for the FDA to identify a modification process that could yield a device with performance or safety attributes that are *less than new*, the FDA's definition of *remanufacturing* is in stark contradiction to the commonly accepted, and nearly universal, definition published by the U.S. International Trade Commission (USITC):

> *Remanufacturing*: "An industrial process that restores end-of-life goods to original working condition or better. Firms that provide remanufacturing services to restore end-of-life goods to original working condition are considered producers of remanufactured goods."[2]

The ***remanufacturing process*** as known to industries around the world is not new to the medical device industry. It occurs on a daily basis and is considered the highest form of servicing by the FDA. However, in the medical industry, it happens to be called ***refurbishing***. While we encourage the FDA to continue to use the term *refurbishing* to refer to the *remanufacturing process*, we urge the FDA to:

1.) recognize *refurbishing* is an industry-specific name for the *remanufacturing process*

2.) stop using the term *remanufacturing* to define a modification process

3.) change general distinctions from "servicing or remanufacturing" to "servicing or modifying."

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[1] Remanufacturing of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff, U.S. Food & Drug Administration (FDA), 2021

[2] "Remanufactured Goods: An Overview of the U.S. and Global Industries, Markets, and Trade" Report, U.S. International Trade Commission (ITC), Investigation No. 332-525, USITC Publication 4356, Oct. 2012

Industry sectors use different terms to identify the *remanufacturing process*—and that is completely acceptable—as long as that sector's term aligns with the USITC definition of a process that "restores end-of-life goods to original working condition or better."[3] For instance, in the automotive and commercial vehicle sectors, the term is *remanufacturing* itself; in aviation and aerospace, the reference is *maintenance, repair and overhaul (MRO)*; and for medical devices, consumer goods and electronics, the term is *refurbishing*.

In fact, according to the USITC, "… most U.S. remanufacturers of medical imaging equipment identify themselves as refurbishers rather than remanufacturers because of the specific regulatory definition of 'remanufacturer' provided by the U.S. Food and Drug Administration (FDA)."[4]

Remanufacturing—a key driver of a strong circular economy focused on sustainability—represents an important and growing segment of U.S. manufacturing. The USITC definition of *remanufacturing* is widely recognized across key industry sectors. The foundation of it appears in federal legislation[5] and is used by other government agencies, including the Office of the United States Trade Representative (USTR), U.S. Customs and Border Protection (CBP), and the U.S. Federal Trade Commission (FTC).

A universal meaning of the term *remanufacturing* strengthens the Biden administration's commitment to equity and the Paris Climate Agreement. It will provide consumers with consistent information to make purchase decisions, as well as promote a stronger circular economy for all Americans.

The influence of the USITC definition of *remanufacturing* goes beyond U.S. borders. In 2016, six leading industry associations—in Brazil, China, the European Union, and the United States—reached agreement on an international industry definition of *remanufacturing*. The international definition was aligned purposefully with the USITC definition.

> "*Remanufacturing* is a standardized industrial process by which [previously sold, worn or non-functional products] are returned to same-as-new, or better, condition and performance. The process is in line with specific technical specifications, including engineering, quality and testing standards. The process yields fully warranted products."[6]

It is worth noting that the clause "or better" in both the USITC definition and the international definition does *not* refer to any change in intended use of the original good;

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[3] *Ibid.*
[4] *Ibid.*
[5] Public Law 114-65
[6] Remanufacturing Associations Agree on International Industry Definition, European Association of Automotive Suppliers (CLEPA), MERA - The Association for Sustainable Manufacturing, Automotive Parts Remanufacturers Association (APRA), Automotive Parts Remanufacturers National Association (ANRAP), European Organization for the Engine Remanufacture (FIRM) and Remanufacture Committee of China Association of Automobile Manufacturers (CPRA), Sep. 2016

rather, it recognizes that improvements in condition, performance, or both may be engineered into the remanufactured good following a root cause analysis.

The FDA's definition of *refurbish* is clearly aligned with both the international definition and the USITC definition of *remanufacturing*. All three definitions refer to a servicing process that restores products, in the FDA's words, "to be like new." On the other hand, the FDA's definition of *remanufacture* refers to a modification process that "significantly changes" critical characteristics of a device so that it is *no longer like new*.

> *Recondition/Refurbish/Rebuild*: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair of components, installation of OEM provided updates and upgrades, and replacement of worn parts. [7]
>
> *Remanufacture*: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[8]

For all practical purposes, the FDA's definition of *refurbish[ing]*, the USITC definition of *remanufacturing*, and the international definition of *remanufacturing* are equivalent, even synonymous. It is the subsequent use by the FDA of the word *remanufacture* to define a modification process that is the cause of major concern. This current practice is the source of potential major harm to the reputation of all other industries around the world that truly remanufacture goods.

Case in point, in the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, published in 2018, the FDA wrote, "We have concluded, a majority of comments, complaints, and adverse event reports alleging that inadequate 'servicing' caused or contributed to clinical adverse events and deaths actually pertain to 'remanufacturing' and not 'servicing.'"[9]

We are aligned with the FDA's stated goal to help promote clarity among definitions, and we seek the FDA's support to affect positive change. The medical device industry is the only known U.S. industry that refers to the *remanufacturing process* as *refurbishing* (or one of the other acceptable USITC terms), and then misapplies the term *remanufacturing* to a modification process that yields devices that are not comparable to new. In an effort to protect and strengthen the good name associated with the *remanufacturing process* across

[7] Remanufacturing of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff, U.S. Food & Drug Administration (FDA), 2021
[8] *Ibid*.
[9] FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, U.S. Food & Drug Administration (FDA), 2018

all industry sectors, we urge the FDA to strongly consider our request for change before issuing final guidance.

The Importance of Remanufacturing to the U.S. Economy

According to the USITC, "In addition to offering 'like new' functionality, remanufactured goods allow producers to considerably lessen their capital production costs and give consumers access to like-new products at lower prices than new goods. Moreover, remanufacturing has lower environmental impacts than producing new goods, since it requires less material and energy. Remanufacturing occurs across a diverse range of U.S. industries and types of firms, including large original equipment manufacturers (OEMs), independent suppliers, and small and medium-sized enterprises (SMEs). U.S. firms have been involved in remanufacturing for decades, and the United States is the leading global producer, consumer, and trader of remanufactured goods."[10]

The U.S. Congress recognized the importance and value of remanufactured components as exemplified by the 2015 Federal Vehicle Repair Cost Savings Act[11] which requires federal agencies to encourage the use of remanufactured parts when maintaining federal vehicle fleets.

These examples demonstrate how companies in the U.S. and the international remanufacturing community have made great strides to positively influence the perception and trade of remanufactured goods. Common terminology will only enhance collective efforts to lower and eliminate non-tariff trade barriers and raise consumer awareness and acceptance of remanufactured goods.

Conclusion

Achieving clarity of definitions and distinction among defined terms is a stated goal of the FDA. While we recognize the legacy with regard to the term *remanufacturing* in the medical device industry, the time is right to bring clarity and meaningful change to a multitude of constituencies, not the least being consumers and patients.

We urge the FDA to take a leadership role and harmonize the medical device industry's definition of *remanufacturing* with all other industries that remanufacture goods in the U.S. and abroad. Such action will align the FDA with other government agencies and industry sectors, curtail confusion among consumers, and help elevate remanufacturing as an environmentally responsible process that yields high-quality, like-new goods.

In closing, we appreciate the opportunity to submit comments and are available to further discuss the importance of this request. For further information, please contact us at jchalifoux@mera.org or 248-750-1280.

[10] "Remanufactured Goods: An Overview of the U.S. and Global Industries, Markets, and Trade" Report, U.S. International Trade Commission (ITC), Investigation No. 332-525, USITC Publication 4356, Oct. 2012
[11] Public Law 114-65

Sincerely,

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