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February 25, 2019

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

RE: Medical Device Servicing and Remanufacturing Activities; Public Workshop; Request for Comments (Docket No. FDA-2018-N-3741)

Dear Commissioner and Staff:

The Motor & Equipment Manufacturers Association (MEMA) and its remanufacturing division, MERA - The Association for Sustainable Manufacturing, submit these comments to the U.S. Food & Drug Administration (FDA) on the 2018 White Paper and Public Workshop: "Evaluating Whether Activities are Servicing or Remanufacturing." With roots in the transportation industry, MERA represents the interests of the broader remanufacturing community across multiple industry sectors. For that reason, we attended the Public Workshop on Dec. 10-11, 2018, and file these written comments on the need for common terminology and the use by the FDA of the term "remanufacturing."

MEMA and MERA urge the Administration to stop using the term "remanufacturing" to identify a 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 process that could negatively modify an existing device, calling it "remanufacturing" contradicts the commonly accepted definition published by the U.S. International Trade Commission (USITC). According to the USITC, remanufacturing is "an industrial process that restores end-of-life goods to original working condition or better."[2]

Remanufacturing – a key driver of a circular economy – represents an important and growing segment of U.S. manufacturing. The USITC definition of remanufacturing is widely recognized across key industry sectors. It appears in federal legislation 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).

[1] White Paper: Evaluating Whether Activities are Servicing or Remanufacturing, U.S. Food & Drug Administration (FDA), 2018
[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

To emphasize our point on common terminology, different industry sectors use different terms to identify the *remanufacturing process* – and that is completely acceptable – as long as that sector's term refers to "an industrial process that restores end-of-life goods to original working condition or better." 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 consumer goods and electronics, the term is *refurbishing*. According to the USITC, "Finally, 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)."[3]

As noted, the remanufacturing process is significantly different than how it is represented by the FDA; therefore, another term is needed by the FDA to properly identify a device that has been altered and no-longer complies with its reported, intended use. Calling this "remanufacturing" is inaccurate, misleading to consumers and a risk to patient safety. In essence, we are simply asking the FDA to call it something else.

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."[4]

The U.S. Congress recognized the importance and value of remanufactured components as exemplified by the 2015 Federal Vehicle Repair Cost Savings Act[5] which requires federal agencies to encourage the use of remanufactured parts when maintaining federal vehicle fleets. The MEMA Washington, D.C. office and MERA were influential in the passage of this key legislation.

Internationally, "Remanufacturing is a standardized industrial process by which [previously sold, worn or nonfunctional products] are returned to same-as-new, or better, condition and performance. The process is in line with specific technical specifications,

[3] "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
[4] *Ibid.*
[5] Public Law 114-65

including engineering, quality and testing standards. The process yields fully warranted products."[6]

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.

Quality. Value. Green.

MEMA, through its MERA division, is elevating the perception of remanufacturing in the marketplace. Our members not only communicate that remanufacturing is manufacturing, they emphasize that remanufactured products are produced in a factory setting.[7] Furthermore, MERA is the home of Manufactured Again Certification, where manufacturing and remanufacturing are held to the same international quality standards. The program, based on ISO 9001, also promotes corporate social responsibility, particularly environmental stewardship.

MEMA represents more than 1,000 motor vehicle suppliers that manufacture and remanufacture components and systems for use in passenger cars and heavy trucks.[8] The motor vehicle components manufacturing industry is the nation's largest sector of manufacturing jobs – employing over 871,000 workers in all 50 states – and contributes nearly $435 billion in U.S. GDP.

The MERA network of remanufacturers, suppliers, universities, and professional services firms promotes the economic, environmental and product performance benefits of remanufactured goods. Remanufacturers support at least 180,000 full time jobs in the United States.[9]

Conclusion

The importance of definitions and common terminology was recognized by the FDA and attendees during the Public Workshop in December 2018.

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[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

[7] 16 CFR Part 20: Guides for the Rebuilt, Reconditioned and Other Used Auto Parts Industry; Final Revisions to the Guides, U.S. Federal Trade Commission (FTC), Jul. 2014

[8] MEMA represents the full spectrum of vehicle suppliers through its four divisions: Automotive Aftermarket Suppliers Association (AASA), Heavy Duty Manufacturers Association (HDMA), MERA - The Association for Sustainable Manufacturing and Original Equipment Suppliers Association (OESA)

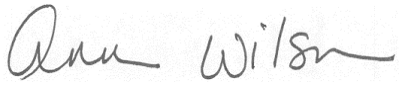
[9] "Remanufactured Goods: An Overview of the U.S. and Global Industries, Markets, and Trade" Report, U.S. International Trade Commission (ITC), Investigation No. 332-525, USITC Publication 4356, Oct. 2012

MEMA and MERA urge the FDA to recognize today's commercial reality and no longer use the term "remanufacturing" when referring to a modification process that "significantly changes the finished device's performance or safety specifications, or intended use." By doing so, the FDA will align with other government agencies and industry sectors; curtail confusion among consumers; lower the risk to patient safety; and advance the U.S. economy and international trade.

In closing, MEMA and MERA 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.

Sincerely,

John Chalifoux
President & Chief Operating Officer, MERA
Vice President, MEMA



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The Association for Sustainable Manufacturing
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