HENRY SCHEIN®
Henry Schein, Inc. • 135 Duryea Road • Melville, NY 11747

DIRECT PHONE: 631-414-8385
DIRECT FAX: 631-414-8394
nap.monroe@henryschein.com

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Dr. David W. Feigal, Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT: Medical Device User Fee Modernization Act (MDUFMA)
Section 301: Identification of Manufacturer Labeling Requirement
Docket 02N-0534

Dear Dr. Feigal:

On behalf of Henry Schein, Inc., the largest distributor to the U.S. office-based healthcare market[1], I am submitting these comments regarding MDUFMA Section 301. These comments further define and amplify similar concerns raised by and/or discussed with the American Dental Trade Association (ADTA), the Dental Dealers of America (DDA), the Dental Manufacturers of America (DMA), the Health Industry Distributors Associations (HIDA), and the Medical Device Manufacturers Association (MDMA), regarding MDUFMA.

MDUFMA Section 301(a) provides that a device will be deemed misbranded:

> Unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.

The legislative history of Section 301 makes clear that when Congress enacted the new legislation, it did not fully understand the existing laws and regulations governing medical devices. For example, in the House Report on MDUFMA, Congress noted that "Under current law, manufacturers are required to put their names on the packaging of a device, but not on the device itself."[2] In point of fact, current laws and regulations require device

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[1] For additional information regarding Henry Schein, Inc., please see www.henryschein.com.
[2] House Report 107-728, Part 2 to H.R. 3580, page 9, "Medical Device User Fee and Modernization Act of 2002," Committee on Energy and Commerce, October 15, 2002.

packaging to bear a label with the name and address of the manufacturer, packer, OR distributor.[3] This basic misunderstanding of current law apparently precluded Congress from fully appreciating the adverse consequences of Section 301.

The legislative history further indicates that Congress likely initially intended the new requirement to better control reprocessing of single use devices. While there is obvious merit to improving the identification of such products because packaging is discarded after the initial use, Congress unnecessarily expanded the new requirement to all medical devices. Indeed, the final legislation not only requires a totally new level of labeling on all medical devices themselves, but imposes a labeling requirement that is inconsistent with previous legislation regarding medical device labeling.

As MDUFMA stands, requiring the name of the manufacturer to appear on each device will adversely affect both consumers and the healthcare industry. At a minimum, the requirements of Section 301 will increase healthcare costs and create consumer confusion by:

1. requiring new labeling for all products on the devices themselves, unless the requirement is specifically waived. Please consider the implications of labeling each glove and gauze pad with the name of the manufacturer. (The specific waiver provision in 301(a) seems to have been drafted to apply to devices which could be subject to reprocessing. The list of specific waivers for simple disposable devices will be quite long and may be difficult to administer.)

2. requiring consideration of revised labeling on existing packaging for thousands of medical device products in order to ensure consistency between the names shown on the packaging and on the device.

3. jeopardizing the viability of many contract manufacturers and the production strategies of many manufacturers' branded and private label companies.

4. negatively affecting the competitive structure of the U.S. medical device industry. (The U.S. medical device industry is one of few with a positive trade balance.)

5. adversely affecting consumer brand confidence in existing products.

6. reducing the possibilities for, and the value of, private labeling by distributors. (Private labeling is a widely recognized tool for keeping consumer costs low.)

In order to address these issues, Henry Schein, Inc. proposes the following:

a. FDA should consider adopting the position that the new labeling requirement of Section 301 should be applied only to reprocessed medical devices, but waived as not feasible for all other medical devices.

b. For all other medical devices, FDA should continue to enforce the labeling requirements of 21 U.S.C. § 352(b)(1) and 21 C.F.R. § 801.1(c), as these requirements are adequate to ensure the proper identification of a responsible party thereby enhancing consumer protection.

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[3] 21 U.S.C. § 352(b)(1) and 21 C.F.R. § 801.1(c).

c. In order to clarify the applicability of Section 301 in accordance with Paragraph a above, FDA should (i) seek an amendment to Section 301 that makes clear that the new labeling requirement applies only to reprocessed devices, and (ii) in the meantime, issue a statement indicating that it will exercise enforcement discretion until the law is amended.

It is important that FDA quickly address this matter so that Industry does not face the costly burden of adding to and changing labeling on a large percentage of medical devices sold in the U.S. Because the new law becomes effective in just over 1 year, Industry seeks to better understand -- as quickly as possible -- its obligations so that it may plan appropriately to ensure compliance.

I look forward to working with FDA, ADTA, DDA, DMA, HIDA, and MDMA and others toward devising a unified approach in the best interest of the healthcare consumers and the industry which serves them.

Best regards,

Napoleon (Nap) Monroe
Vice President
Corporate Brand Development

NM:bam

cc: Dr. Mark McClellan, FDA Commissioner
Daniel Troy, Esq., FDA Chief Counsel
Mr. Timothy Ulatowski, CDRH
Mr. Harold A. Pellerite, CDRH
Mr. Casper E. Uldriks, CDRH
Dr. Lireka Joseph, CDRH
Dockets Management Branch (Docket 02N-0534)
Ms. Jennifer Alfisi, HIDA
Dr. H. Neal Dunning, DMA Regulatory Affairs Consultant
Mr. John Eldred, DMA
Mr. Mark B. Leahey, MDMA
Mr. Gary Price, ADTA__
Dr. Ed Shils, DDA
Ms. Janet Trunzo, AdVamed