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AdvaMed Statement on FDA Medical Device Labeling Meeting

WASHINGTON, D.C. – Jeff Secunda, vice president, technology and regulatory affairs, for the Advanced Medical Technology Association (AdvaMed), issued the following statement regarding today’s FDA public meeting on medical device labeling:

“AdvaMed appreciates FDA providing the opportunity for all stakeholders to offer input on the agency’s proposals to develop an on-line repository of medical device labeling and to make device photographs available in a public database. The medical technology industry is committed to providing patients and physicians with useful and understandable information so they can make informed decisions about medical treatment options and the operation and maintenance of their devices.

“However, we are concerned that making medical device labeling broadly available via an on-line repository may inadvertently lead to public confusion, as many device labels contain technical or complex information intended for hospitals or practitioners and may not be clearly understandable to the lay audience. We also question whether such a repository advances public health and are concerned whether the significant FDA resources needed to maintain it are justified.

“Regarding the availability of device photographs in a public database, depending on the level of detail required, such photographs could provide proprietary information to competitors, both domestic and outside the U.S.

“We look forward to working with FDA and other stakeholders as it refines these proposals and are committed to providing patients and physicians with meaningful information about devices and diagnostics.”

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AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit www.advamed.org.