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

<http://www.regulations.gov>

Re: Docket No. FDA-2009-N-0441; Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools

Dear Sir or Madam:

Covidien is submitting these comments in response to a request from the United States Food and Drug Administration ("FDA" or "Agency") for comments on the use of the Internet and social media to promote FDA-regulated medical products. 74 Fed. Reg. 48083 (September 21, 2009).

Covidien is a manufacturer of a diverse range of products organized in three segments: Medical Devices, Pharmaceuticals, and Medical Supplies. We are committed to compliance with the laws and regulations governing the advertisement and promotion of the regulated products we manufacture and sell and welcome the opportunity to comment on this important topic. Covidien is a member of the Advanced Medical Technology Association ("AdvaMed") and we endorse the comprehensive comments submitted by AdvaMed on this topic.

In addition to endorsing AdvaMed's comments, Covidien would like to reinforce the importance of the distinction of regulatory authority by the FDA over the advertising of prescription drugs and restricted devices versus the regulatory authority by the Federal Trade Commission (FTC) over advertising of Class I and Class II devices. Any FDA guidance on the topic of promotional activities of medical products using the Internet or social media should take this distinction into consideration. This is particularly important in the area of providing appropriate risk information. While the law requires advertisements for prescription drugs and restricted devices to provide a brief summary or brief statement of the warnings, precautions, side effects and contraindications associated with the product, there is no similar provision for the advertising of unrestricted devices. See 21 U.S.C. §352(n), (r). While there is no question that appropriate information about regulated products, including information on risk, must be

included in promotional materials, the differences in legal requirements as well as distribution, use, and application between prescription drugs and devices should be accounted for in any guidance developed by the Agency that addresses the use of the Internet and social media for promotional activities of FDA-regulated products.

Another important distinction between the regulation of the promotion of prescription drugs and devices relates to the requirement for drug manufacturers to submit to the FDA any “labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product.” 21 C.F.R. § 314.81(b)(3). No similar requirement for submission of advertising exists for manufacturers of any class of device. The FDA’s question about how to reconcile posting of real-time information on social media with the requirement to submit promotional materials to the Agency is necessarily focused on prescription drugs. We would ask that the FDA remain mindful of the distinction between prescription drugs and devices in any guidance document developed to address the promotional use of the Internet and social media.

Without limiting the foregoing, Covidien also would like to submit additional comments with regard to the use of the Internet and social media in the marketing and advertising of drugs and devices. In brief, a prescription drug or device manufacturer should be held accountable for only the dissemination of content over which it has reasonable and direct control. Moreover, the FDA should not require prescription drug or device manufacturers to act as *de facto* law enforcement over content that is beyond their direct control. Current and future Internet technologies provide opportunities for third parties neither regulated by the FDA nor under the control of a prescription drug or device manufacturer to disseminate product information that may be inaccurate or otherwise incomplete. From a legal perspective, prescription drug and device manufacturers often do not have a right of action against what is considered “protected free speech” under the First Amendment even if such speech is either erroneous or harmful. Even in circumstances where a prescription drug or device manufacturer has a right of action under laws such as the Lanham Act, the lack of geographical boundaries for such third parties and site operators (many of whom may operate from locations outside the United States) make it nearly impossible either to apply personal jurisdiction or enforce judgments.

In addition, the FDA should acknowledge that control, forms and formats of the Internet and social media are not uniform. Any new regulatory requirements should take into account these differences as highlighted in attached flow diagram (see Figure 1 attached).

Finally, the current FDA regulations and guidance regarding direct-to-consumer (“DTC”) advertising should apply to the Internet and social media as well. However, the FDA should consider altering the current standards to accommodate the limitations of any particular communications vehicle. For example, Twitter has a 140 character limit that impacts the ability of drug or restricted device manufacturers to provide Important Risk Information (“IRI”) or fair balance; however, Twitter permits the inclusion of shortened Uniform Resource Locators (“URLs”), such as TinyURLs. A drug or restricted device


manufacturer, after self-identifying as such to its Twitter followers, could make a general statement about one of its products and include a TinyURL that could direct consumers to the manufacturer's web site that has more comprehensive safety information about its product.

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Thank you for the opportunity to provide comments on this interesting topic.

Respectfully submitted,

COVIDIEN

By: 
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Attachment

FIGURE 1. SUMMARY OF FORM, FORMAT AND LEVEL OF CONTROL WITH REGARD TO THE INTERNET AND SOCIAL MEDIA

