

events within the protections of the Patient Safety Act and Patient Safety Rule. As a result, healthcare providers, and those committed to improving the safety and quality of patient care, have a strong interest in the integrity of PSOs and their ability to carry out this statutory mission.

AHRQ administers the provisions of the Patient Safety Rule relating to listing and operation of PSOs, which are the focus of this guide. The HHS Office for Civil Rights is responsible for enforcing the confidentiality protections of the Patient Safety Act and Patient Safety Rule.

For an entity to be listed, and remain listed, as a PSO, the Patient Safety Rule relies primarily upon a system of attestations. An entity seeking listing for a three-year period as a PSO must submit to AHRQ a form, Certification for Initial Listing, to attest that it meets the Patient Safety Rule's eligibility and listing requirements at the time the entity submits its certifications. During its period of listing, a PSO must submit a form, Two Bona Fide Contract Requirement, every two years attesting that it has at least two contracts with different providers. If the PSO has other relationships, specified in section 3.102(d)(2), with any contracting provider, it must also submit the form, PSO Disclosure Statement, regarding its relationships with the provider and attest to the completeness and accuracy of its disclosures. Finally, a PSO must submit the form, Certification for Continued Listing, to seek continued listing for an additional three-year period and attest that it meets the requirements for continued listing. This process places the burden for understanding and complying with the Patient Safety Rule on the PSO.

The Patient Safety Rule also authorizes AHRQ to assess or verify PSO compliance with the rule's requirements at any time through requests for information or by conducting announced or unannounced reviews of, or site visits to, PSOs (section 3.110). In addition to routine compliance reviews, AHRQ may also conduct site visits or request additional information if, for example, AHRQ becomes aware that a PSO is not in compliance with the requirements of the statute or the Patient Safety Rule.

The Patient Safety Rule provides PSOs latitude in complying with its requirements. In part, this reflects a recognition that PSOs will vary in terms of size, complexity, and sophistication and, over time, PSOs will vary significantly in the breadth and scope of their activities. For example, PSOs can be local, regional, or national in

orientation; they can focus narrowly or broadly in terms of the clinical or analytic services they offer providers; they can target their services toward one type of healthcare facility or multiple healthcare settings; and, they are likely to vary in the sophistication and complexity of information technology employed.

Each PSO will need to develop its approach to compliance by taking into account the specific mission it has chosen for itself, the specific activities and expertise it offers to healthcare providers, and its size and mode of operation. As a consequence, AHRQ developed this self-assessment guide recognizing that individual PSOs are likely to approach compliance from different perspectives. Thus, the guide does not propose a uniform approach to compliance. Instead, the guide presents sample questions—some of which may not be applicable or appropriate to a specific PSO—to encourage each PSO to take a comprehensive and systematic approach to compliance that best meets its circumstances.

The questions in the guide do not establish new standards or requirements; they are only presented for an illustrative purpose. If there is any inadvertent discrepancy between the text of the guide and the Patient Safety Rule, PSOs should consider the text of the rule as authoritative.

More information on the "Patient Safety Organizations: A Compliance Self Assessment Guide" and PSOs can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/index.html>.

Dated: September 11, 2009.

**Carolyn M. Clancy,**

*Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0441]

#### Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER), in collaboration with FDA's Center for

Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), and Center for Devices and Radiological Health (CDRH), is announcing a public hearing to discuss issues related to the promotion of FDA-regulated medical products (including prescription drugs for humans and animals, prescription biologics, and medical devices) using the Internet and social media tools. FDA is seeking participation in the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, Internet vendors, advertising agencies, and the regulated industry. This meeting and the written comments are intended to help guide FDA in making policy decisions on the promotion of human and animal prescription drugs and biologics and medical devices using the Internet and social media tools. FDA is seeking input on a number of specific questions but is interested in any other pertinent information participants in the hearing would like to share.

**Dates and Times:** The public hearing will be held on November 12 and 13, 2009, from 8 a.m. to 5 p.m. each day. Submit written or electronic registration by close of business on October 9, 2009. Written and electronic comments will be accepted until February 28, 2010.

**Location:** The public hearing will be held at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202-314-6305; Metro: L'Enfant Plaza station on the yellow, green, orange, and blue lines; see: <http://ntsb.gov/events/newlocation.htm>. (FDA has verified the Web site address, but FDA is not responsible for any changes to the Web site after this document publishes in the **Federal Register**.)

**ADDRESSES:** Submit written registration and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic registration and electronic comments, identified with the docket number found in brackets in the heading of this document, to <http://www.regulations.gov>.

Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the hearing (see section VI of this document).

**Registration to Attend and/or to Participate in the Meeting:** Seating at the hearing is limited. People interested in attending should submit written or electronic registration as specified above

(see **ADDRESSES**) by close of business on October 9, 2009. Registration is free and will be accepted on a first-come, first-served basis. Written or electronic comments will be accepted until February 28, 2010.

The procedures governing the hearing are found in 21 CFR part 15 (see section IV of this document). If you wish to make an oral presentation at the hearing, you must state your intention on your registration submission (see **ADDRESSES**). To speak, submit your name, title, business affiliation, addresses, telephone and fax numbers, and e-mail address. FDA has included questions for comment in section III of this document. You should also identify by number each question you wish to address in your presentation and the approximate time requested. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Once FDA notifies registered participants of their scheduled times, presenters should submit to FDA two copies of each presentation to be given (see **FOR FURTHER INFORMATION CONTACT**).

If you need special accommodations because of a disability, please inform Jean-Ah Kang (see **FOR FURTHER INFORMATION CONTACT**) at the time of registration.

**FOR FURTHER INFORMATION CONTACT:** Jean-Ah Kang, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3270, Silver Spring, MD, 20993-0002, 301-796-4269, FAX: 301-796-8444, e-mail: [InternetPublicMeeting@fda.hhs.gov](mailto:InternetPublicMeeting@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Internet has become a widely used medium for companies, including manufacturers, packers, or distributors of medical products regulated by FDA, to disseminate information about their products. The Internet's ability to facilitate communication, information sharing, information exchange between systems, user-centered design, and collaboration has also evolved as a result of the second generation of Web development and Web design, or "Web 2.0." Web 2.0 has led to the emergence of a variety of social media tools (i.e., Web properties whose online content is

primarily created and published by users rather than the property owners).

The continually evolving nature of the Internet, including Web 2.0 and social media tools, as well as their expansion to applications such as mobile technology, have raised questions and concerns over how to apply existing regulations to promotion in these newer media. FDA is evaluating how the statutory provisions, regulations, and policies concerning advertising and promotional labeling should be applied to product-related information on the Internet and newer technologies. Although the agency believes that many issues can be addressed through existing FDA regulations, special characteristics of Web 2.0 and other emerging technologies may require the agency to provide additional guidance to the industry on how the regulations should be applied.

**A. Regulation of Advertising and Labeling**

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has responsibility for regulating the labeling of prescription drugs and medical devices and the advertising of prescription drugs and restricted medical devices. If an activity or material is considered to be either advertising or labeling, it must meet certain requirements.

Under section 201(m) of the act (21 U.S.C. 321(m)), labeling is defined as "all labels and other written, printed, or graphic" materials "upon" or "accompanying" an article. The term "accompanying" has been broadly defined by the Supreme Court (*Kordel v. United States*, 335 U.S. 345, 349-350 (1948)). FDA's regulations give examples of labeling materials, including brochures, mailing pieces, detailing pieces, calendars, price lists, letters, motion picture films, and sound recordings (§ 202.1(l)(2) (21 CFR 202.1(l)(2))).

FDA regulates the labeling of all drugs and devices under its jurisdiction. Labeling must be truthful and nonmisleading (section 502(a) of the act (21 U.S.C. 352(a))).

FDA also regulates the advertising for prescription drugs and biologics. Although the act does not define what constitutes an "advertisement," FDA generally interprets the term to include information (other than labeling) that is issued by, or on behalf of, a manufacturer, packer, or distributor and is intended to promote a product. This includes, for example, "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media

such as radio, television, and telephone communication systems" (§ 202.1(l)(1)). According to the act (section 502(n)), a prescription drug is misbranded if its advertising does not include, in addition to the product's established name and quantitative composition, a "true statement" of information in brief summary "relating to side effects, contraindications and effectiveness" of the advertised product. For prescription drug advertisements, FDA's implementing regulations (21 CFR part 202) specify that, among other things, the statutory requirement of a "true statement" is not satisfied if an advertisement is false or misleading with respect to side effects, contraindications or effectiveness or if it fails to reveal material facts about "consequences that may result from the use of the drug as recommended or suggested in the advertisement" (§ 202.1(e)(5)). The prescription drug regulations also specify that advertisements must "present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug," which is achieved when "the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety" (§ 202.1(e)(5)(ii)).

FDA similarly regulates advertising for restricted devices. A "restricted device" is a device that may be restricted to sale, distribution, or use only with the written or oral authorization of a licensed practitioner, or in accordance with other conditions if FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness (21 U.S.C. 360j(e)). FDA also restricts devices through the approval orders granted to many class III devices (21 U.S.C. 360e(d)(1)(B)(ii)). According to the act, a restricted device is misbranded if its advertising is false or misleading in any particular (section 502(q) of the act), or if its advertising does not contain a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications (section 502(r) of the act). There are currently no regulations establishing specific requirements for the content and format of advertisements for restricted devices.

Although FDA has not comprehensively addressed when Internet promotion of prescription drugs and medical devices is labeling versus advertising, the agency has jurisdiction over all prescription drug and biologic product promotion as well as all restricted device advertising and all

device promotional labeling when conducted by or on behalf of a manufacturer, packer, or distributor. There are no regulations that specifically address Internet promotion separately from the other types of promotion discussed above, nor are there any regulations that prohibit the use of certain types of media to promote drugs and medical devices. Although no rule has specifically addressed Internet promotion, it is fairly clear that some promotional efforts are substantially similar in presentation and content to promotional materials in other media or publications. At the same time, FDA recognizes that the Internet possesses certain unique technological features and that some online tools that may be used for promotion offer novel presentation and content features. Another emerging issue involves the reporting of adverse event data because such information may initially be revealed using social media platforms in the context of Internet promotion for FDA-regulated medical products.

#### B. 1996 Meeting on Promotion of FDA-Regulated Products on the Internet

On October 16 and 17, 1996, FDA held a public meeting to discuss issues related to the promotion of FDA-regulated medical products on the Internet (see 61 FR 48707, September 16, 1996). The agency's objective was to receive broad public input and to hear various points of view and opinions on Internet issues from a discussion among interested persons. A discussion group format was used and covered the following topics: Investigational product information, chatrooms and newsgroups, and Web site links. A transcript of the meeting is available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm175775.htm>.)

#### C. New Internet Tools and Technology

Since the 1996 public meeting, there has been a massive expansion of new tools and technologies, such as blogs, microblogs, podcasts, social network sites ("social networks") and online communities, video sharing, widgets, and wikis, which are defined as follows:<sup>1,2</sup>

- **Blogs** (e.g., *Blogger*, *WordPress*, *TypePad*): Blogs are Web sites with regular updates (in reverse chronological order—newest update at the top) that typically combine text,

images (graphics or video), and links to other Web pages. Blogs are usually informal and take on the tone of a diary or journal entry. Some blogs are very personal, while others provide mainstream news updates. Most blogs encourage dialogue by allowing their readers to leave comments.

- **Microblogs** (e.g., *Twitter*): Microblogs are comprised of extremely short written blog posts, similar to text messages, and provide real-time updates. Twitter is an example of a popular microblog service that lets users broadcast short messages up to 140 characters long ("tweets") using computers or mobile phones.

- **Podcasts** (e.g., *audio sharing*): Podcasts (a blend of the terms "iPod" and "broadcast") are audio or video files that users can listen to or watch on computers or on a variety of portable media devices (like an iPod, Zune, and certain cell phones). Podcasts are usually short and often free, and users can arrange via subscription to receive new podcasts automatically via their computers or other media devices.

- **Social networks and online communities** (e.g., *Facebook*, *MySpace*, *LinkedIn*, *Friendster*, *Sermo*): Social networks and online communities give users opportunities to connect with or provide resources to clients, colleagues, family, and friends who share common interests. In many social networks, users create profiles and then invite people to join as "friends." There are many different types of social networks and online communities, many of which are free, and they range from general to those tailored for a specific demographic or interest area.

- **Video sharing** (e.g., *YouTube*, *Blip.tv*, *Vimeo*): Also called a "video hosting service," video sharing allows individuals to upload video clips to an Internet Web site. The video host will then store the video on its server and show the individual different types of code to allow others to view or comment on the video.

- **Widgets**: Supposedly short for "window gadget," a widget is a graphic control on a Web page that allows the user to interact with it in some way. Widgets can also be easily posted on multiple Web sites, have the added benefit of hosting "live" content, and often take the form of on-screen tools (clocks, event countdowns, auction-tickers, stock market tickers, flight arrival information, daily weather, etc.).

- **Wikis** (e.g., *Wikipedia*, *Medpedia*): The term "wiki" comes from the Hawaiian word for "fast." Wiki technology creates a Web page that anyone with access can modify—quickly and easily. A wiki can be either

open or closed, depending on the preferences of the community using it. An open wiki allows anybody to make changes and view content. A closed wiki allows only community members to make changes and view its content. Some wikis allow anyone to view content but only members to edit the content.

As the use of social media tools on the Internet has proliferated, the agency has engaged in a fact-finding process by communicating with companies, third-party providers, trade associations, and other groups to gain a better understanding of the nature of, and the technical aspects to, promotion of FDA-regulated medical products using these tools. FDA appreciates the time and effort that these individuals, companies, and associations have invested in assisting the agency in understanding the challenges and issues involved with Internet promotion using these newer Web 2.0 technologies.

## II. Purpose and Scope of the Hearing

This hearing is intended to provide an opportunity for broad public participation and comment concerning Internet promotion of FDA-regulated medical products, including human and animal prescription drugs and biologics and medical devices. Please note that this hearing does not address nonprescription drug promotion. FDA is particularly interested in hearing views from the public as to how expanding Web 2.0 technologies may be used to promote medical products to both health care professionals and consumers in a truthful, nonmisleading, and balanced manner. In addition, FDA is seeking public comment on Internet adverse event reporting.

## III. Issues for Discussion

Questions have arisen regarding the application of the prescription drug and device advertising and labeling provisions, regulations, and policies of promotion on the Internet, especially with regard to the use of emerging technologies such as blogs, microblogs, podcasts, social networks and online communities, video sharing, widgets, and wikis. This section briefly discusses the issues the agency has identified as most frequently raised by regulated companies and other interested parties. It should be noted that although a question may raise a particular issue, that does not necessarily mean that the agency will issue guidance or a regulation on that issue.

The agency invites comment at the public hearing on the general concept of Internet promotion, positive or negative; on any aspect of Internet promotion that

<sup>1</sup> Adapted from <http://newmedia.hhs.gov/socialmedia101.html> Social Media 101 Overview: The WHAT and the WHY. Accessed on August 14, 2009.

<sup>2</sup> Adapted from [http://www.usa.gov/webcontent/technology/other\\_tech.shtml](http://www.usa.gov/webcontent/technology/other_tech.shtml) Social Media and Web 2.0 in Government. Accessed on August 14, 2009.

is of interest to the presenter; and on the topics outlined in the following paragraphs. We are specifically interested in data and research on the use of social media tools in promotion, including data from companies on their own experiences, the extent to which health care professionals and consumers are using and are influenced by various social media tools, and the impact of Internet and social media promotion on the public health.

1. For what online communications are manufacturers, packers, or distributors accountable?

FDA regulates promotion of medical products that is conducted by or on behalf of a manufacturer, packer, or distributor. In determining whether a manufacturer, packer, or distributor is accountable for a communication about its product(s), the agency considers whether the manufacturer, packer, or distributor or anyone acting on behalf of the manufacturer, packer, or distributor, such as an ad agency, created the promotional communication. In addition, the agency considers whether the manufacturer, packer, or distributor or anyone acting on behalf of the manufacturer, packer, or distributor is influencing or controlling the promotional activity or communication in whole or in part.

Manufacturers, packers, and distributors may have a variety of options for how much control they exert over activities on the Internet, regardless of whether the promotional activity occurs on company-sponsored venues or on third-party venues. For example, in setting up a program about its product(s) through a chatroom, a manufacturer, packer, or distributor may allow comments to be posted in real time with no editing or review by the manufacturer, packer, or distributor; alternatively, the manufacturer, packer, or distributor may have the option of reviewing and editing comments before they are posted. Furthermore, the manufacturer, packer, or distributor may have control over the length of time comments are visible. As a result, information may be available to a much broader audience than originally engaged in the communication or program if the comments/entries are posted for an indefinite period of time ("archived materials"). Similarly, a manufacturer, packer, or distributor posting a video on a video-sharing site such as YouTube may choose whether or not to allow viewers to post comments.

In addition, various Web sites and tools can allow manufacturers, packers, or distributors to prompt others to

communicate about their products. For example, a manufacturer, packer, or distributor may ask or otherwise encourage users to post their own videos about its product(s) on sites such as YouTube. A manufacturer, packer, or distributor may also send out packets of information to prominent bloggers with the aim of prompting the blogger to write about its product(s). Alternatively, a manufacturer, packer, or distributor may create an online community for patients or health care professionals to discuss disease states, which may prompt discussion about the manufacturer's, distributor's, or packer's product(s). The agency is interested in hearing the views of the public on the following topics:

- What parameters or criteria should be applied to determine when third-party communications occurring on the Internet and through social media technologies are subject to substantive influence by companies that market products related to the communication or discussion?

- In particular, when should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?

- How should companies disclose their involvement or influence over discussions or material, particularly discussions or material on third-party sites?

- Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? If so, what are these considerations?

- With regard to the potential for company communications to be altered by third parties, what is the experience to date with respect to the unauthorized dissemination of modified product information (originally created by a company) by noncompany users of the Internet?

2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing submission requirements) in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs, mobile technology)?

FDA's regulations require that any promotional communications that make claims about a company's product include certain required disclosures,

such as the indicated use of the product and the risks associated with the use of the product (note that "reminder" promotion, which calls attention to the name of a product but does not make any representations or suggestions about the product, is exempt from these disclosure requirements (see 21 CFR 200.200, 201.100(f), 201.105(d)(2), 202.1(e)(2)(i), 801.109(d)). The prescription drug regulations also require that drug advertisements present a fair balance between information relating to risk and information relating to benefit (§ 202.1(e)(5)(ii)). They also specify that risk information must be presented with a prominence and readability reasonably comparable to claims about drug benefits (§ 202.1(e)(7)(viii)). Furthermore, for advertisements to be truthful and nonmisleading, they must contain risk information in each part as necessary to qualify any representations and/or suggestions made in that part about the drug (§ 202.1(e)(3)(i)). Similarly, section 502(r) of the act requires a "brief statement" of intended use and relevant risk information for restricted device advertising. In addition, section 201(n) of the act provides that a determination of whether product advertising or labeling is misleading relies in part on the extent to which labeling or advertising reveals facts material with respect to possible consequences of the use of the products as represented in the labeling or advertising material. Except for medical device applicants, applicants are also responsible for submitting copies of promotional materials to FDA (see, e.g., §§ 314.81(b)(3)(i), 314.550, 314.640, 514.80(b)(5)(ii), 601.12(f)(4), 601.45, and 601.94 (21 CFR 314.81(b)(3)(i), 314.550, 314.640, 514.80(b)(5)(ii), 601.12(f)(4), 601.45, and 601.94)).

- How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?

- Are there data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health?

- Are there proposed solutions that may help address regulatory concerns when using social media tools associated with space limitations or tools that allow for real-time communications to present product information?

- How should companies address the potential volume of information shared on various social media sites with regard to real-time information that is continuously posted and regulatory

requirements to submit promotional materials to FDA as applicable (see, e.g., §§ 314.81(b)(3)(i), 314.550, 314.640, 514.80(b)(5)(ii), 601.12(f)(4), 601.45, and 601.94)?

3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

Some manufacturers, packers, or distributors have expressed a desire to correct what are, in their belief, misconceptions or misinformation about their products, including unapproved uses of their products that are being conveyed on a Web site outside their control, such as on a blog, social networking site, or a wiki Web site (i.e., Wikipedia). Other companies have stated that they have not corrected what they believe is misinformation in the belief that they could be viewed by such an action as being responsible for all the information on the target Web site rather than just the information that they post or submit.

- The agency is interested in any data or research on how companies have approached these issues.

- Are there any parameters or criteria that could be used to determine the appropriateness of correcting misinformation and/or scope of information a company can provide when trying to correct misinformation on a Web site outside a company's control?

- Should the parameters differentiate with regard to the prominence of the third-party site (i.e., readership), its intended audience (e.g., general public, health care professionals, patients), its intended purpose (e.g., personal diary, encyclopedia-type reference), and/or the author of the information on the site?

4. When is the use of links appropriate?

The Internet allows users to move easily between Web sites or sources that provide information on many related topics. Under the act, companies are prohibited from promoting approved human and animal drugs, biologics, and medical devices for unapproved uses. However, sponsors sometimes provide links from their branded (e.g., mentions a product) Web sites to other informational sources about diseases, such as support groups, some of which may contain information about unapproved disease conditions or unapproved uses of approved products. Furthermore, some companies are using unbranded (e.g., does not mention a product) uniform resource locators (URLs) that, when clicked on, take users directly to branded information.

- The agency is interested in any comments about the appropriateness of

various techniques regarding the use of links (including between various social media tools) and data or research about whether or not users find these approaches to be misleading.

- Should parameters be established for links to and from Web sites?

- In addition, the agency is interested in any data or research concerning the frequency with which users actually click on different categories of links (e.g., banner ads, links within Web sites, sponsored links, organic search result links) to get additional information about products.

5. Questions specific to Internet adverse event reporting

FDA regulations require the submission of postmarketing adverse event reports.

For drugs, adverse event reporting obligations are described for approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and prescription drugs marketed without an approved application under §§ 310.305, 314.80, and 314.98 (21 CFR 310.305, 314.80, and 314.98, respectively). For new animal drugs, adverse event reporting obligations are described for approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) under § 514.80. Licensed manufacturers that hold biological license applications (BLAs) are also subject to adverse event reporting requirements under § 600.80 (21 CFR 600.80). These regulations cover requirements for submission of individual case safety reports on either an expedited basis (i.e., 15-day "Alert reports") or on a less frequent (periodic) basis, as specified in the regulations.

Nonprescription (over-the-counter or OTC) drugs marketed without an approved application also have reporting obligations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462). Under this act, reports of serious adverse events associated with OTC products must be submitted to FDA within 15 days.

FDA's Medical Device Reporting (MDR) regulation, 21 CFR part 803, requires medical device manufacturers to identify and monitor significant adverse events involving their medical devices. The regulation requires manufacturers of medical devices to report device-related deaths, serious injuries, and malfunctions to FDA whenever they become aware of information that reasonably suggests that a reportable event occurred (i.e., one of their devices has or may have caused or contributed to the event).

The expectation is that entities responsible for reporting will promptly review all adverse event information received or otherwise obtained, which potentially includes information from the Internet and social media tools. According to FDA's March 2001 draft guidance for industry entitled "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines" (available at <http://www.fda.gov/downloads/Biologics/BloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm092257.pdf>), adverse experience information that is submitted via the Internet to an entity with postmarketing reporting obligations under §§ 310.305, 314.80, and 600.80 should be reported to FDA if there is knowledge of the four basic elements for submission of an individual case safety report (see section IV.B in the draft guidance). The draft guidance also states that those entities should review any Internet sites sponsored by them for adverse experience information, but are not responsible for reviewing any Internet sites that they do not sponsor; however, if they become aware of an adverse experience on an Internet site that they do not sponsor, they should review the adverse experience and determine if it should be reported to FDA. For OTC products, the July 2009 guidance for industry entitled "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application" (available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm171672.pdf>) lists the Internet as an example of a means for a reporter to convey adverse event information associated with an OTC product to the responsible person (i.e., "manufacturer, packer, or distributor whose name \* \* \* appears on the label of an OTC drug marketed in the United States without an approved application").

With the increasing use of Web-based technology by manufacturers of FDA-regulated medical products, health care systems, and patients, and the continual emergence of different types of Web-based media, FDA is interested in hearing the views of the public on the following topics related to Web-based media:

- How are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products?

- How is adverse event information from these sources being received, reviewed, and processed?
- What challenges are presented in handling adverse event information from these sources?
- What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

#### IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

#### V. Comments

Regardless of attendance at the public hearing, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://>

[www.regulations.gov](http://www.regulations.gov). It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: September 16, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Request for Information Regarding Development and Operation of a Transplantation Sentinel Network

**AGENCY:** Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services.

**ACTION:** Request for information notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) is seeking information on development and operation of a national transplantation sentinel network (TSN) for the United States, including resources needed for management of such a system. The purpose of the network is to detect and prevent disease transmission from organ and tissue allografts recovered for transplantation.

In June 2005, the CDC announced a Request for Application (RFA) through a cooperative agreement for development of a TSN for organizations that recover, process, distribute, and implant organs and tissues. The overall goal of the system was to improve patient safety for organ and tissue recipients. The RFA objectives were to: (1) Identify and track organs and tissues to facilitate intervention following recognition of infections among recipients or donors; (2) improve communication among those in the transplant community, healthcare facilities and public health agencies concerning potential risks for transmission of infections; and (3) improve pathologic and microbiologic capabilities on cadaveric donor

specimen samples through shared resources. Development and field testing of the prototype was completed in 2008.

For this RFI, respondents are asked to describe experiences, plans or opinions regarding aspects of completing and operating a TSN system; system governance, security, and marketing; user training; and operational and infrastructure management. Responses need not address every aspect of this RFI; responses may be limited to address specific components or portions of a section. The specific sections requested for comments are: (1) Transition of Transplantation Transmission Sentinel Network (TTSN) Prototype to Full Production; (2) Standardization and Compatibility Issues; (3) Reporting Criteria; (4) Interoperability and Interfacing with Existing Data Sources; (5) System Operation and Infrastructure Management; (6) Analysis Plan including Feedback to Users; (7) Patient Health Information Privacy and Security; and (8) System Governance.

**DATES:** Comments must be submitted on or before December 11, 2009.

**ADDRESSES:** The entire TSN RFI can be accessed at [http://www.dev.cdc.gov/ncidod/dhqp/pdf/ttsn/RFI\\_TSN\\_FedRegDoc\\_9909.pdf](http://www.dev.cdc.gov/ncidod/dhqp/pdf/ttsn/RFI_TSN_FedRegDoc_9909.pdf). Electronic responses are preferred and should be sent to [TransplantRFI@cdc.gov](mailto:TransplantRFI@cdc.gov).

Responses sent in hard copy format must be securely bound and sent to Debbie Seem, Office of Blood, Organ and other Tissue Safety, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Building 16, MS-A07, 1600 Clifton Road, NE., Atlanta, GA, 30329-4018, Telephone number: 404-639-3234, E-mail Address: [gqi4@cdc.gov](mailto:gqi4@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Each year in the United States, more than 28,000 solid organs and 2 million tissues are transplanted, including heart, lung, liver, kidneys, pancreas, intestine, bone, skin, heart valves, tendons, fascia and corneas. Donor-derived infections have been identified as a source of morbidity and mortality among both solid organ and tissue transplant recipients.

Infectious transmission identified in the past few years among solid organs have reflected a broad array of viruses, bacteria, and parasites, resulting in a high proportion of mortality amongst infected recipients; examples include HIV, hepatitis C virus (HCV), lymphocytic choriomeningitis virus, *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Strongyloides spp.*, and *Trypanosoma cruzi*, the etiologic agent of Chagas Disease.