

Exhibit Halls

What exhibitors need to know about the FDA's authority.

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The beginning of the calendar year marks the beginning of the new season for meetings. Exhibit halls are packed with sponsors displaying their latest and greatest technologies. As with every other aspect of medical devices, there are regulatory restrictions on what can and cannot be displayed and discussed at the booths. We talked with Harold (Wally) Pellerite, Assistant to the Director for the Office of Compliance; Deborah Wolf, Regulatory Counsel; and Cap Uldrks, Special Assistant to the Director for the Office of Compliance, to clarify the FDA's influence on exhibiting marketed and investigational medical devices.

Q: Can anyone and everyone be exhibitors at meetings in the US?

A: Yes, unless the FDA has taken a specific enforcement action involving a firm or individual that prohibits them from marketing a device.

Q: Can OUS companies without devices marketed in the US exhibit at meetings?

A: Yes, as long as the company does not plan to market the exhibited device in the US. Otherwise, the device must comply with the statutory and regulatory requirements for entering a device into interstate commerce. For example, the company must declare the devices they wish to exhibit to US Customs as entering the US for display only at a trade show, and the devices must be returned following the exhibition. In addition, the company is prohibited from selling the device to or taking orders from customers. All devices and information pertaining to the devices must clearly identify that the device is not approved for use in the US.

Q: Can OUS companies with only investigational devices in the US exhibit at meetings?

A: Yes, but only in order to encourage participation of clinical investigators and enrollment of subjects in a clinical study. Again, the company is prohibited from selling the device to or taking orders from customers, and all devices and information pertaining to the devices must clearly identify that the device is not approved for use in the US.

Q: Can a sponsor exhibit under an Application Integrity Policy (AIP)?

A: Whether a device may be exhibited by a firm under an AIP would depend on the facts and circumstances of each individual case. Basically, sponsors under an AIP are limited to exhibiting devices that are already available on the market or under review by the FDA. However, a firm under an AIP that wants to know if a particular product may be exhibited should contact the ODE/OIVD Integrity Officer, Carl DeMarco at (301) 594-2022, extension 134.

Q: Is there anything in the law or regulations, or is this just linked to promotion?

A: The laws and regulations are specifically applicable to promotional practices. In addition, the FDA addresses promotion through nonbinding guidance. However, unacceptable promotion of a device violates Section 501 and 502 of the Food, Drug and Cosmetic Act and is prohibited under Section 301 of the Act. Devices that are the subject of such promotion are determined to be adulterated or misbranded.

Q: Is it appropriate to have investigational devices on display if they are identified as such?

A: Yes, investigational devices must be clearly identified as investigational but sponsors cannot make any claims of safety or effectiveness of the device because these claims can only be made after clearance or approval of the device by the FDA. In addition, the company is prohibited from selling the device to or taking orders from customers at the exhibit.

Q: Does there need to be a separate area for OUS companies?

A: Devices that are available for marketing OUS must be separated from investigational devices or devices marketed in the US. Unapproved devices must be clearly marked as not approved in the US.

Q: What can companies do at trade shows (eg, recruit investigators, take orders, register for training programs)?

A: Companies can recruit investigators, however, sponsors cannot take orders or register physicians for training programs unless the device is cleared or approved.

Q: Are there any nuances to the rules for devices that are almost FDA approved? For example, if an advisory panel has recommended approval with conditions, can the sponsor begin recruiting doctors for training programs?

A: Any decisions regarding devices that are almost approved, that is, the firm has received an Approvable Letter, are determined by the Agency on a case-by-case basis. Companies may identify physicians that would like to be trained and the FDA may permit training to start in specific cases; however, companies should contact the FDA to determine if they may proceed with their training program. Shipping a device to a physician who is not a clinical investigator under an approved IDE would be considered commercialization and in violation of the Act.

Q: What materials can be distributed for investigational devices?

A: Informational materials may be distributed but should be limited to scientific information or clinical study information. For example, sponsors may distribute literature to physicians in order to recruit clinical investigators. Providing information regarding the safety and effectiveness of an investigational device is prohibited. In addition, all materials must indicate that the device is investigational and not approved for use.

Q: What materials can be distributed for OUS devices, not yet marketed or investigated in the US?

A: Materials may be displayed for OUS devices if the company does not intend to market or study the device in the US; however, providing US physicians with such material may be viewed as promoting the use of unapproved devices, which is prohibited.

Q: What materials can be distributed for devices marketed in the US (ie, are there limitations regarding off-label use, etc.)?

A: Materials containing information regarding off-label use of medical devices may not be distributed at an

exhibit. Such information may be considered by the FDA as intended to change the product's intended use. Peer-reviewed literature or clinical case studies published in medical journals may be provided, but not in proximity to the device if the information discusses off-label use. Such material should be provided to the FDA for review before the information is distributed.

“Materials containing information regarding off-label use of medical devices may not be distributed at an exhibit.”

Q: Is there active enforcement of the rules?

A: Yes, the FDA does take enforcement or legal action against companies that inappropriately promote their products.

Q: What are the consequences of breaking the rules?

A: Violation of the Act can result in a number of sanctions. Violative devices are subject to seizure. Persons and firms in violation are subject to injunction, prosecution, or civil money penalties of \$15,000 per violation up to a total of \$1 million for the firm and each responsible individual. While seizures, injunctions, and prosecutions are legal actions filed in court, civil money penalties are administrative and may be imposed by the Director of the Center for Devices and Radiological Health without a court decision.

Q: Where can additional information be found regarding exhibiting at meetings?

A: Compliance Policy Guide 300.600 provides information regarding the commercial distribution of medical devices and may affect a firm's promotional activities and can be found on the FDA's Web site at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg300-600.html. Information regarding compliance and enforcement with the Act is also available on the FDA Web site at <http://www.fda.gov/oc/industry/default.htm>. ■

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