Guidance for Industry and FDA Staff

Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects

Good Guidance Practice Level 2

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring

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Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, (HFZ-312), 2094 Gaither Road, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Viola Sellman at (301) 594-4723.

Additional Copies:

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Guidance for Industry and FDA Staff on Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects

This guide is intended to clarify section 812.7 of 21 CFR Part 812, the regulations providing procedures for investigational device exemptions (OMB CONTROL NUMBER 0910-0078). This section prohibits the promotion or test marketing of investigational medical devices. Any person wishing to make known through a notice, publication, display, mailing, exhibit, announcement, or oral presentation the availability of an investigational device for the purpose of obtaining clinical investigators to participate in a clinical study involving human subjects should:

1. Announce the availability of the device only in medical or scientific publications or at medical or scientific conferences whose readership or audience is comprised primarily of experts qualified by scientific training and experience to investigate the safety and effectiveness of devices.

2. State in clear terms that the purpose is only to obtain investigators and not to make the device generally available. Enrolling more investigators than necessary to evaluate the safety and effectiveness of the device will be considered promotion or commercialization of the device.

3. Limit the information presented in any notice of availability to the following: the proposed use of the device, the name and address of the sponsor, how to apply to be an investigator, and how to obtain the device for investigational use. The notice should further list the investigator's responsibilities during the course of the investigation; namely, to await institutional review board (IRB) and Food and Drug Administration (FDA) approval before allowing any subject to participate, to obtain informed consent from subjects, to permit the device to be used only with subjects under the investigator's supervision, to report adverse reactions, to keep accurate records, and, more generally, to conduct the investigation in accordance with the signed

agreement with the sponsor, the investigational plan, FDA's regulations, and whatever conditions of approval are imposed by the reviewing IRB or FDA.

4. Use direct mailing for the sole purpose of soliciting qualified experts to conduct investigations. (Note: an undirected mass mailing will not be considered an appropriate means of soliciting clinical investigators. Such a mailing will be considered promotion.)

5. Include the following statement displayed prominently and in printing at least as large as the largest printing in the notice: "Caution – INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE."

6. Ensure that no claims are made which state or imply, directly or indirectly, that the device is reliable, durable, dependable, safe, or effective for the purposes under investigation or that the device is in any way superior to any other device.

7. Not present comparative descriptions of the device with other devices but may include reasonably sized drawings or photographs of the device.

8. A sponsor or investigator should not offer volume discounts for an investigational device. FDA would regard such discounts as the promotion of an investigational device.

When recruiting study subjects, sponsors and investigators should take the following into consideration:

1. Direct recruiting advertisements are seen as part of the informed consent and subject selection process [see 21 CFR 50.20, 50.25, 56.111(a)(3) and 812.20(b)(11)]. IRB review is necessary to ensure that the information provided is not misleading to subjects. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

2. When direct advertising is used, the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

3. No claims should be made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any device.

4. Advertising for recruitment into investigational device studies should not use the term “new treatment,” without explaining that the test article is investigational. A phrase such as “receive new treatments” implies that all study subjects will be receiving newly marketed products of proven worth.

5. Advertisements should not promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisement may state that subjects will be paid, but should not emphasize the payment or the amount to be paid.

Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. The following should be included in advertisements, but FDA does not require inclusion of the listed items:

1. The name and address of the clinical investigator and/or research facility;

2. The condition under study and/or the purpose of the research;

3. In summary form, the criteria that will be used to determine eligibility for the study;

4. A brief list of participation benefits, if any (e.g., a no-cost health examination);

5. The time or other commitment required of the subjects; and

6. The location of the research and the person or office to contact for further information.

This guide represents the Agency's current thinking on preparing notices of availability of investigational medical devices and for recruiting study subjects. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

References:

Investigational Device Exemptions Manual (FDA 96-4159)

Title 21 Code of Federal Regulations, Part 812