The FDA Reauthorization Act of 2017 (FDARA), signed into law on August 18, 2017, amended several sections of the Federal Food, Drug, and Cosmetic Act. This document was developed and issued prior to the enactment of FDARA, and certain sections may no longer be current as a result. FDA is assessing how to revise this document to represent our current thinking on this topic. For more information please contact CDRH-FDARA@fda.hhs.gov.

Contains Nonbinding Recommendations

Guidance for Industry, FDA Staff, and FDA-Accredited Third Parties

Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)

Document issued on: March 2, 2009

This document supersedes the document which was issued on September 15, 2005

The information collection provisions in this guidance have been approved under OMB control number 0910-0569. This approval expires April 30, 2018. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

For questions regarding this document, contact CDRH, Office of Compliance, Accredited Persons Program at CDRHOCAccrPersProg@fda.hhs.gov or 301-796-5500 for CDRH issues or the Office of Compliance and Biologics Quality, Division of Case Management at 301-827-6201 for CBER issues.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov//MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1532 to identify the guidance you are requesting.

Or

Office of Communication, Training and Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N,
Rockville, MD 20852-1448
Phone: 800-835-4709 or 301-827-1800
Internet: http://www.fda.gov/cber/guidelines.htm

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Guidance for Industry, FDA Staff, and FDA-Accredited Third-Parties

Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Manufacturers Of Medical Devices May Be Eligible To Have Third-Party Inspections Of Their Establishments

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the voluntary third-party inspection program initially established by law in 2002, and applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria (see 21 USC §374(g)). The Inspection by Accredited Persons Program (AP Program), allowed eligible manufacturers to elect to have third parties that have been accredited by FDA (Accredited Person or AP) conduct some of their inspections instead of FDA. Under that 2002 law, manufacturers of eligible medical devices requested prior approval to use an AP instead of FDA staff to conduct a Quality Systems (QS) regulation inspection of their facilities.

Changes Made by FDAAA

FDAAA Section 228 amended the program by revising the eligibility criteria, making it easier to participate in the AP program. FDA prior approval of such inspections is no longer necessary.

Instead, manufacturers need only provide notification of their intent to use an AP to conduct such inspections.

In addition, AP's who conduct inspections under this program shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

Potential Benefits of AP Program

A benefit of the AP program is that it allows eligible manufacturers greater control over the timing of their inspections. In addition, some of the APs accredited by FDA are already recognized by other countries as persons authorized to conduct ISO 13485 audits of device establishments. A single AP inspection may meet the requirements of more than one regulatory authority, thereby reducing the need for multiple inspections of the same establishment.

This guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use such a program. Any establishment that is interested in obtaining additional information about eligibility or other matters addressed in this document should address the contacts listed on the cover of this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOmbudsman/default.htmCBER Ombudsman information can be found at http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm122881.htm

II. Discussion

Under Section 510(h) of the Food, Drug and Cosmetic Act (the Act), domestic manufacturers of class II or class III medical devices are subject to inspection for compliance with QS regulation requirements (21 CFR Part 820) and other applicable requirements at least once every two years.

(See 21 U.S.C. 360(h)). The AP inspection program permits eligible manufacturers to schedule qualified independent third-parties to perform an inspection required under section 510(h) or for an establishment required to register under section 510(i) (21 U.S.C. 360(h),(i)). To be eligible,.the previous completed FDA or AP inspection for establishment must have resulted in a "No Action Indicated" (NAI) or "Voluntary Action Indicated" (VAI) inspection.

Manufacturers customarily schedule a series of partial inspections to be performed by qualified independent third-parties to comply with international and national regulatory standards as required for conformity assessment purposes by jurisdictions other than the United States. Likewise, manufacturers may rely on a single comprehensive inspection or a series of partial inspections that would cumulatively constitute a complete inspection for the purposes of meeting FDA's biennial inspection requirement.

FDA accredits APs to perform inspections under the FDA AP Program (21 U.S.C. 374(g)(1)). APs must be independent without conflicting ties (21 U.S.C. 374(g)(3)(B). Many APs who were selected for this program are already eligible to conduct independent inspections. Others are still in the process of completing training. Training of APs consists of a combination of classroom and cooperative audits with FDA. Inspection reports prepared by the independent APs are reviewed by FDA to determine whether your firm is in compliance with the QS regulation and other applicable requirements. FDA maintains a list of trained independent APs which is available on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm You may select any of the APs listed, provided you meet all of the eligibility criteria for the AP Program.

The next section of this guidance describes in detail the eligibility criteria applicable to manufacturers who wish to participate in the AP Program. The submission and review of such inspection reports will provide the Agency with valuable information about the quality of medical devices marketed in the United States, thereby allowing FDA to focus its limited inspectional resources on those products that pose the greatest risk to public health. Nothing in the provisions authorizing the AP program affects FDA's authority under the act to inspect any device establishment (21 U.S.C. 374(g)(9)).

III. Information about How to Participate in the AP Program

A. AP Eligibility Requirements

1. Who may participate in the AP Program?

The AP Program is open to domestic U.S. device establishments and foreign establishments that are required to register with FDA under section 510(i) of the Act, provided such establishments otherwise meet the program's eligibility criteria.

2. What are the eligibility requirements for participating in the AP Program?

Based on the requirements found at Section 704(g) of the Act, you must satisfy the following five criteria in order to be eligible to participate in the program:

1. You "manufacture, prepare, propagate, compound, or process" class II or class III medical devices (see 21 U.S.C. 374(g)(1)) The shorthand term "manufacture" will be used for convenience throughout this document instead of repeatedly listing each of these activities (i.e., "manufacture, prepare, propagate, compound, or process");

2. You market at least one of the devices in the United States (see 21 U.S.C. 374(g)(6)(A)(ii)(IV)(bb));

3. You market or intend to market at least one of the devices in one or more foreign countries that certifies, accredits, or otherwise recognizes the AP you have selected as a person authorized to conduct inspections of device establishments (see 21 U.S.C. 374(g)(6)(A)(ii)(IV)(bb)),

4. Your most recent complete inspection performed by FDA, or by an AP under this program, was classified by FDA as either NAI or VAI.[1] (21 U.S.C. 374(g)(6)(A)(i)) ; and

5. You submit a notice to FDA that includes (21 U.S.C. 374(g)(6)(A)(ii)((I-IV)):
    - the date of last inspection and classification of that inspection;
    - a statement of the intention of the owner or operator to use an accredited person to conduct inspections;
    - the identification of the particular AP you intend to select to conduct the inspection;
    - a certification that at least one of the devices you manufacture is marketed in the United States, and such devices are marketed, or intended to be marketed in one or more foreign countries, one of which recognizes the person accredited as a person authorized to conduct inspection of device establishments.

[1] The phrase "complete inspection" as used in this document is intended to include situations in which a full inspection may be comprised of two or more cumulative partial inspections performed by the AP during the course of a two year period. Where an inspection consists of a series of partial inspections, FDA ordinarily would expect to issue only one classification decision after the conclusion of the complete inspection.

B. Device Eligibility Requirements[2]

1. Is your medical device eligible?

Only establishments that manufacture devices that are either class II or class III may be eligible for inspection under the AP Program (21 U.S.C. 374(g)(1)). In addition, to be eligible, at least one of these devices must be marketed in the United States and at least one must be marketed, or intended to be marketed, in one or more foreign countries (21 U.S.C. 374(g)(6)(A)(ii)(IV)). FDA cannot waive these requirements or provide a variance.

If you do not manufacture a class II or a class III device, market at least one such device in the United States, and market or intend to market at least one such device in a foreign country, your establishment is not eligible for inspection under the AP Program.

2. How can you show that you market or intend to market a device in a foreign country?

The following are examples of ways you can show that you market or intend to market a device in a foreign country:

- a distribution agreement, purchase order, or order acknowledgement issued by a foreign customer;
- a marketing application submitted by your firm to a foreign government; or
- appropriate clearance documents from the foreign government to your firm.

3. Is it necessary that one of the devices marketed or intended to be marketed in a foreign country is a class II or class III device?

Yes. At least one of the devices that you market in the United States must be a class II or class III device, and at least one of the devices you manufacture for commercial distribution in a foreign country must be a class II or class III device (21 U.S.C. 374(g)(1)(6)(A)(ii)).

We recommend that you include the specific name(s) of the device(s) and, as applicable, the PMA or 510(k) number(s) of the class II or III devices in your notification to FDA of intent to use an AP.

The device you market in the United States and the device you market or intend to market in one or more foreign countries do not have to be the same device, as long as they are manufactured in the same establishment.

[2] Unless otherwise noted, a reference to "requirements" in the sections that follow refer to the requirements under 21 U.S.C. 374(g).

C. Foreign Country-Related Eligibility Requirements

1. What do you need to know about the inspection process of the foreign country or countries where you will market your medical device?

At least one foreign country where you market or intend to market your class II or class III device must certify, accredit, or otherwise recognize the AP you have chosen as a person authorized to conduct device inspections (21 U.S.C. 374(g)(6)(A)(ii)(IV)(bb)).

For example, one foreign country where you market or intend to market the device may certify the person you selected as an AP as authorized to conduct inspections of device establishments. This would satisfy the condition of recognition by a foreign country of the AP you selected.

2. How can you identify APs that are recognized by a foreign country as authorized to conduct inspections of device establishments?

FDA's Internet site mentioned earlier (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm) lists the APs approved by FDA and provides information on APs that are recognized by foreign countries. We recommend that you verify that the foreign country recognizes the AP before hiring the AP to conduct an inspection of your manufacturing facility.

D. Inspectional History

1. How does your inspection history affect your participation in the AP Program?

Your most recent FDA-classified device inspection is one of the factors that determine your eligibility to participate in the AP Program (21 U.S.C. 374(g)(6)(i)).

Inspections are classified according to these three categories.

No Action Indicated (NAI)

This means there were no deviations found during the inspection or only minor deviations from the applicable QS/GMP requirements. (See 21 U.S.C. 360j(f)(1)(A) and regulations at 21 CFR Part 820).

Voluntary Action Indicated (VAI)

This means deviations from minor to a significant nature for which the establishment failed to meet QS/GMP requirements were found during the inspection.

Official Action Indicated (OAI)

This refers to significant QS/GMP deviations that were found during the inspection and regulatory action by FDA should be recommended.

Refer to Field Management Directive-86 (FMD-86) for a further description of FDA's classification criteria at http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061430.htm

You may qualify for the AP Program if your most recent complete device inspection, performed either by FDA or by an AP under the AP Program, was classified by FDA as either NAI or VAI (21 U.S.C. 374(g)(6)(A)(i)).

In addition, in assessing your eligibility to use an AP, FDA may ask you to provide compliance data including complete reports of QS regulation inspectional findings from audits that occurred at your firm within the past 24 months (21 U.S.C. 374(g)(6)(B)(iii)). FDA may also ask you or the AP you selected for information concerning the relationship between your firm and the AP (21 U.S.C. 374(g)(6)(B)(ii)(II)).

2. What information should I submit concerning my firm's inspectional history?

To facilitate our review of your recent inspectional history, your notification of intent to participate in the program should include the information described below.

The date of your firm's most recent device inspection that was classified by FDA. As stated previously, to be eligible, your most recent device inspection performed either by FDA or by an AP under the AP Program, must have been classified as NAI or VAI (21 U.S.C. 374(g)(6)(A)(i)).

If you received a list of inspectional observations at the conclusion of the inspection, please provide a copy with your notice. FDA uses Form FDA-483 to record inspectional observations.

We also recommend you provide FDA a copy of the inspection report provided to you by the AP after the inspection.

3. Does an OAI classification from FDA mean that I cannot participate in the AP Program?

Not necessarily. In the case of a device establishment for which FDA classified the results of the most recent inspection of the establishment by an AP as OAI, the establishment may petition FDA to determine its eligibility for further AP inspections (21 U.S.C. 374(g)(6)(C)).

The device establishment should meet all the other eligibility requirements and explain in the petition how it has corrected the violations.

4. Will manufacturers need to notify the FDA to schedule the same AP for each partial inspection?

No. The same AP may conduct partial inspections that ultimately will represent one completed comprehensive inspection for purposes of complying with applicable regulatory

requirements. In this situation, the two year period begins at the time the first partial inspection is initiated.

E. Accredited Person (AP) Selection

1. How do you notify FDA of your intent to use an AP?

You may select an AP from the list on the FDA website previously mentioned, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm

Submit a written notification to FDA identifying the AP you intend to use (21 U.S.C. 374(g)(6)(A)(ii)(III)).

FDA will review the notification and either deny clearance to participate; or may request additional information. If FDA requests compliance data or other information, FDA must make a decision about your eligibility to use an AP, and about your AP selection, within 60 days after you provide the requested information. If FDA does not notify you of its decision within 60 days, your firm is deemed to have clearance to have an inspection performed by the AP you have selected (21 U.S.C. 374(g)(6)(B)(iv)).

If FDA denies your firm's notification to use an AP or rejects its selection of an AP, FDA will provide your firm with a statement of the reason(s) for its decision (21 U.S.C. 374(g)(6)(B),(C)).

If FDA does not deny your notification to use the AP you have selected, you are responsible for paying the AP for its services. The amount of compensation is to be determined by agreement between your firm and the AP (21 U.S.C. 374(8)).

F. Notification of Intent To Participate in the AP Program

1. Does my notice have to be in a particular format?

No. However, your notice should identify the AP you have chosen and include information that shows you meet the eligibility criteria (21 U.S.C. 374(g)(6)(A)). If a foreign country recognizes the AP you selected as a person authorized to conduct inspections of device establishments, you may support your statement to that effect by referring to any relevant information from FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/default.htm

2. Will FDA notify you if your notification is not complete?

Yes. If FDA needs more information about your firm, its inspectional history, the AP you have chosen, or other eligibility criteria, the Agency will contact you within 30 days. If FDA does not respond within 30 days after it receives your notification, your selection is deemed approved, and you may make arrangements for the AP you have selected to inspect your facility (21 U.S.C. 374(g)(6)(B)(i)).

3. Where should you send your notification of intent to participate?

For devices regulated by CDRH, you should send your notification of intent to participate in the AP Program to:

Office of Compliance
AP Program Coordinator
Office of Compliance
Building 66, Room 3426
Center for Devices and Radiological Health
10903 New Hampshire Avenue,
Silver Spring, MD 20993.

For devices regulated by CBER, you should send your notification of intent to participate in the AP Program to:

Division of Case Management (HFM-610),
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

Notifications to FDA by AP's who conduct inspections under this program of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard for any device establishment should be sent to the address' identified above.

4. Does the AP Program affect other FDA agreements and obligations?

Inspections conducted under the AP Program do not affect FDA's other agreements or operations, or change obligations concerning FDA regulations that affect your device (21 U.S.C. 374(g)(1),(9),(14)).

Although the AP Program makes it possible for eligible device establishments to use third-parties to perform their inspections, nothing in this program affects FDA's broad authority to conduct its own inspections of device establishments under the Act (21 U.S.C. 374(g)(9)).

The provisions of the AP Program do not affect agreements with foreign countries established to carry out the functions of the Office of International Relations at the Department of Health and Human Services (21 U.S.C. 374(g)(14)).

FDA-Accredited Third-Party Inspection Checklist

The checklist below may help you determine whether you qualify for inspection by an FDA-accredited third-party (AP). It is not intended that you submit this checklist to FDA. It is only

an aid to help you assess whether your establishment may be eligible. A QS regulation inspection of your manufacturing operations may be conducted by an AP, instead of by FDA, provided you meet the following four criteria and you notify FDA of your intent to participate in the AP Program.

Your Device

_ 1. You market a class II or class III device in the United States, and
_ 2. You market or plan to market a class II or class III device in one or more foreign countries.

Foreign Government

_ 3. A foreign government in a country where you market or plan to market a class III or class III device selected as a person authorized to conduct device inspections. Check FDA's list of APs at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/Third

History of Inspection

_ 4. Your most recent complete inspection performed by FDA or by an AP under this program was class Action Indicated" (NAI) or "Voluntary Action Indicated" (VAI).