

ORACLE CONSULTING GROUP

FDA's Registration, Listing and U.S. Agent Requirement

A DISCUSSION OF

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FREQUENTLY ASKED QUESTIONS (FAQs)

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WHAT ORACLE CONSULTING GROUP OFFERS

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FDA's New U.S. Registration, Listing and U. S. Agent Requirement

Who: The U.S. Food and Drug Administration (FDA)

What: Published official notice of a "Final Rule" and changes in the registration and listing requirements for foreign firms whose products are imported or offered for import into the U.S., including drugs [amended 21 CFR § 207], biologics [amended 21 CFR § 607] and devices [amended 21 CFR § 807] in the United States.

The changes REQUIRE all foreign drug, biologic and device manufacturers whose products are imported or offered for import into the U.S. to register their firm on FDA form FD-2891, "Initial Registration of Device Establishment," [if previously unregistered] or on their annual update, FDA form FD-2891a, "Registration of Device Establishment," and list their products on FDA form FD-2892, Medical Device Listing. This new regulation ALSO requires foreign FDA regulated firms to identify a U.S.-based Foreign Agent on their registration form and notify FDA about all changes to their identified U.S.-based Agent.

Where: In the U.S. **Federal Register**, the official government publication responsible for announcements related to new regulations and notices of the U.S. Federal Government. See the **Federal Register**: November 27, 2001, Volume 66, Number 228, Rules and Regulations, Pages 59138-59161, or visit the Federal Register Online via GPO Access - wais.access.gpo.gov.

When: This rule is effective February 11, 2002. Compliance date: FDA will begin enforcing the requirements in 21 CFR § 207 [for drug manufacturers] on May 28, 2002, and in 21 CFR § 807 [for device manufacturers] on April 26, 2002.

How: Compliance with this new FDA regulation can be easily accomplished by contracting with Oracle Consulting Group, see "**WHAT ORACLE CONSULTING GROUP OFFERS**" below.

Why: Failure to comply with this regulation could cause FDA to refuse to allow imported devices into the U.S. or request U.S. Customs to impound imported devices awaiting customs release. FDA could take other administrative actions.

FREQUENTLY ASKED QUESTIONS (FAQs)

Note: The majority of these FAQs relate to medical devices questions. The new final rule, as published in the *Federal Register*, covers a number of questions specific to drugs and biologics. To review this document, please have your web browser open:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/112701a.htm>

Question: *What if all our firm does is move an FDA regulated product through a U.S. "Free Trade Zone" without those products ever entering into any U.S. domestic commerce?*

Response: FDA has stated that FDA regulated products that ONLY enter a U.S. "Free Trade Zone" are considered to be outside U.S. Customs territory, however, these products are subject to FDA jurisdiction. FDA has stated that if a foreign establishment sends human drugs, animal drugs, devices, or biological products to a foreign trade zone and the product is re-exported from the foreign trade zone to another country without ever entering U. S. commerce, the foreign establishment is not required to register or list the products that were sent to the foreign trade zone. (These foreign establishments may voluntarily register and list their products, but the new final rule does not require them to do so).

However, if the goods do enter U. S. commerce from a foreign trade zone, the foreign establishment must register and list its products. In this situation, the foreign establishment is like any other foreign establishment that exports a product to the U.S. In other words, if the goods are sold in the United States, the fact that those goods may have initially entered the U.S. through a foreign trade zone does not relieve the foreign establishment from registration and listing requirements.

Question: *If our firm is registered with our own foreign regulatory agency or other regulatory agencies outside the U.S. that have some form of cooperative agreement(s) with the U.S. FDA, does that provide our firm with any form of exemption from U.S. registration and listing?*

Response: No. FDA's cooperative agreements with other regulatory agencies throughout the world do not provide for any exemption from U.S. registration and listing.

Question: *Will the implementation of this new rule cause any disruption or unnecessary delay of our imported goods with U.S. Customs Service?*

Response: No. The U.S. FDA has notified U.S. Customs about this new final rule. Additionally, FDA intends to "phase-in" this rule to allow foreign firms to adjust to these regulatory requirements.

Question: *Can our foreign firm set up a mailbox address or a phone answering machine or answering service to comply with the new rule's requirement for a U.S.-based Agent?*

Response: No. The new rule requires that the U.S.-base Foreign Agent must be physically present in a facility.

Question: *We have multiple products that are regulated by U.S. FDA; do we have to have a separate U.S. Foreign Agent for each product or product line? We already have distributors for each of those lines, could each distributor act as a foreign agent for each line.*

Response: No. Each foreign firm is required to have only ONE U.S. Agent. FDA interprets the underlying Federal law (Act), as allowing only one U.S. Foreign Agent for each foreign establishment.

Question: *Because Canada shares much of its border with the U.S. and has had excellent relations with the U.S. FDA, shouldn't there be an exemption for Canadian firms?*

Response: The underlying Federal law (Act) does not contain any mechanism or criteria for exemptions any foreign firms for any reasons. Therefore, the U.S. FDA cannot provide for any Canadian exemption(s).

Question: *We are concerned that our selection of a U.S. Foreign Agent could create a conflict of interest or loss of confidential or proprietary information.*

Response: FDA cautions foreign firms in their selection of a U.S. Agent precisely for those reasons. It is reasonable to expect your selected U.S. Agent to execute a non-disclosure agreement prior to any discussions regarding that firm acting as your U.S. Agent. It is the policy of Oracle Consulting Group to always initiate U.S. Foreign Agent discussions with the execution of a non-disclosure agreement.

Question: *Is it reasonable to have our U.S. distributor act as our U.S. Foreign Agent?*

Response: Individual situations will vary, however, many foreign firms may determine that the confidentiality and proprietary nature of the relationship with their U.S. Agent excludes their distributor. However, the FDA does not take any position on whether a foreign firm should select a U.S. distributor as its foreign agent.

Question: *Does our U.S. Agent have to file all of our premarket submissions?*

Response: No. The new rule imposes a limited number of duties on the U.S. Agent. Those include assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign firm's products that are imported or offered for import in the U.S. and assisting the FDA in scheduling inspections of the foreign firm. The FDA does not require the U.S. Agent to submit any particular document on behalf of the foreign firm. In cases where FDA is unable to contact the foreign firm "directly or expeditiously," FDA may provide information or documents to the U.S. Agent that is intended to be promptly delivered to the foreign firm.

Question: *Do we have to make all of our contacts with the FDA through our U.S. Agent?*

Response: No. Foreign firms have the discretion of giving their U.S. Agents additional tasks, but foreign firms may always contact FDA directly, with or without their Agent's aid.

Questions: Does our U.S. Agent have any responsibility to act on our behalf to the U.S. Customs Service, or have any responsibility regarding any legal or regulatory issues of our firm's product admissions into the U.S.? Does the U.S. Agent have any legal liability?

Responses: No. However, each foreign firm could request their U.S. Foreign Agent's assistance for issues involving the U.S. Customs Service. FDA does not intend to hold the U.S. Agent responsible for violations of the Act committed by a foreign firm. Violations of the Act and FDA regulations would be pursued against the foreign firm. However, if the U.S. Agent was owned or operated by the foreign firm [effectively the same entity as the foreign firm] and that Agent submitted false information to FDA, FDA could pursue action against that Agent and the foreign firm.

Question: What happens if our foreign firm wants to change its U.S. Agent?

Response: Foreign firms are free to make any changes desired or necessary for their required U.S. Agent. All foreign firms are, however, required to report all such changes, including changes in the new Agent's name, address or phone number, to FDA within ten (10) business days. The new rule allows a foreign firm's U.S. Agent to report those kinds of changes directly to FDA. However, foreign firms are advised to duplicate that reporting effort to ensure compliance.

Question: Do the North American Free Trade Agreement (NAFTA), the U.S.-Canada Free Trade Agreement or the General Agreement on Tariffs and Trade (GATT) restrictions on hindering trade or creating an unreasonable barrier to trade have any effect on this new regulation?

Response: Both GATT and NAFTA permit parties to adopt measures for the protection of human health as well as measures to secure compliance with permissible laws. FDA believes that this new rule accurately implements the legitimate public health objectives of facilitating communication and scheduling of inspections with foreign firms and is not a disguised restriction on trade. Additionally, because the new rule parallels the requirements for domestic registration of providing the name of an accessible individual responsible to the firm, FDA believes this new rule does not violate the national treatment provisions of trade agreements.

Question: We are one of a group of foreign firms that have a U.S. parent owner. Can our U.S. parent company act for all of these foreign firms as a U.S. Agent?

Response: Yes. The new regulation allows U.S. parent companies to register and list on behalf of their foreign subsidiaries.

Question: If a foreign firm only manufactures a component that is used in the manufacture or assembly of a medical device by a U.S. manufacturer, is that foreign firm required to register and list?

Response: No. The new regulation states that a "manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would not otherwise be required to register under the provisions of" this part of the regulation are exempt from the registration requirements.

Question: If our foreign firm manufactures devices that are licensed under section 351 of the PHS Act. Are we required to register and list those products?

Response: Yes. Most of these licensed products are devices that contain or use blood or blood components. Foreign firms that manufacture those licensed products would, in all likelihood, be subject to the registration and listing requirements for blood and blood products, that is 21 CFR § 607 rather than the registration and listing for devices [21 CFR § 807].

Question: Our foreign firm is a contract manufacturer of a medical device for a U.S. firm. Do we have to register and list?

Response: At the current time, no. The current regulation, 21 CFR § 807.20(a)(2) exempts contract manufacturers from listing requirements and 21 CFR § 807.20(c)(1) exempts contract manufacturers from registration and listing. However, FDA is considering additional revisions to 21 CFR § 807 and it is

probable that those revisions will include changes to the requirements for contract manufacturers. Currently FDA “encourages” foreign contract manufacturers to register.

Question: *What is the FDA’s concept of the role of an “official correspondent?”*

Response: The role of the “official correspondent,” for either U.S.-base or foreign device firms, is intended to facilitate communication between the firm’s management and FDA.

Question: *Are we, as a foreign firm, required to have an “official correspondent?” Can that official correspondent be the U.S. Agent?*

Response: Yes, all firms, both U.S.-based and foreign based are required to have an “official correspondent.” Yes, a foreign firm’s U.S. Agent can be the firm’s “official correspondent.” However, foreign firms should fully understand that FDA only allows them to designate their U. S. Agent as their “official correspondent,” and does not require this action. The preamble to the new rule does state that foreign firms may find that designating their U.S. Agent their “official correspondent,” may be more efficient than having two different individuals, one their foreign-based “official correspondent,” and the other their U.S. Foreign Agent.

Question: *I’m confused, what are the differences between our “official correspondent” and our “U.S. Agent?”*

Response: The major role of the “official correspondent” is to facilitate communications between a firm, the firm’s management and FDA across all matters between the firm and FDA. The major role of the U.S. Foreign Agent is to facilitate communications between a foreign firm and FDA for matters related to the foreign firm’s registration and medical device listing(s). The role of the “official correspondent” is broader; the U.S. Agent’s role is narrower. However, the U.S. Foreign Agent, when identified by the foreign firm, can act as both the “official correspondent” and U.S. Foreign Agent. In the latter case, the U.S. Agent would have the responsibility to facilitate all communications between the firm, the firm’s management and the FDA.

Question: *The only devices our foreign firm makes are class I devices. It is our understanding that FDA has determined that these devices present little or no risk to consumers. Are we still required to register, list and identify a U.S. Agent?*

Response: Yes. All U.S. device manufacturers, regardless of device classification, are required to register and list. The responsibilities of your identified U.S. Agent are intended to facilitate FDA’s regulatory oversight regardless of device classification.

Question: *We are a foreign manufacturer of an electronic product, 21 CFR § 1005.25 requires that we designate a permanent resident of the U.S. as our “manufacturer’s agent,” upon whom service of process may be made for and on our behalf [required in section 360(d) of the Radiation Control for Health and Safety Act of 1968]. Can our “manufacturing agent” act as our U.S. Agent?*

Response: Yes. Foreign firms that manufacture products that are both medical devices and electronic products can, if their decision is supported by the requirements of the U.S. Agent, identify their “manufacturer’s agent” as their U. S. Agent.

Question: *What are the schedules for enforcement of the new registration and listing regulations?*

Response: For foreign medical device firms, FDA will begin to enforce the requirements on April 26, 2002. For foreign blood and blood product firms, subject to 21 CFR § 607, only the identification of a U.S. Foreign Agent is required, and FDA’s CBER will contact those firms requesting that information. For foreign drug firms, subject to 21 CFR § 207, FDA will begin to enforce the requirements on May 28, 2002.

Question: *Do I have it right, does this new regulation requires that all foreign medical device manufacturers register, identify an “official correspondent,” identify a U.S.-based Agent, and list every device that is imported into the U.S.?*

Response: Yes. Unless you accomplish all those steps, among other activities to comply with other FDA regulations, you are prohibited from importing medical devices in the U.S.

WHAT ORACLE CONSULTING GROUP OFFERS

Oracle Consulting Group complies with FDA registration regulation requirements and offers its services as an official U.S. Foreign Agent. Those offered services are at two levels:

1) United States Agent (only) in compliance with U.S. FDA regulations 21 CFR § 807 as amended. Services include acting as the **Company's** United States Agent establish and maintain a confidential and proprietary **Company** file, assist the FDA as required, receive FDA documents as required, forward information on FDA contacts and documents to the **Company**, and assist the **Company** with FDA Registration and Listing questions and problems.

2) United States Foreign Agent and Company Official Correspondent in compliance with U.S. FDA regulations 21 CFR § 807 as amended. Services include acting as the **Company's United States Agent and Company Official Correspondent**, perform those duties expected of the **Company Official Correspondent** by FDA, establish and maintain a confidential and proprietary **Company File**, assist the FDA as required, receive FDA documents as required, forward information on FDA contacts and documents to the **Company**, and assist the **Company** with FDA Registration and Listing questions and problems.

As **United States Agent and Company Official Correspondent**, Oracle Consulting Group will provide the **Company** with reminders that will help ensure FDA compliance.

- All **Company** medical device activities are performed in compliance with FDA regulations and premarket submission requirements
- All registration and listing forms are filed with FDA
- All required Corrections and Removal reports are filed with FDA
- All Medical Device Reports are filed with FDA
- All Recalls are filed with FDA

HOW TO RECEIVE A UNITED STATES AGENT AGREEMENT TO REVIEW

Return the FAX BACK – MAIL BACK form on the following page or provide all the appropriate information in an Email to <foreignagent@fdamaze.com>

Make sure you provide the number of listed devices and a brief description of the types of devices you have imported into the U.S.

Upon receipt of your information we will initiate the following steps:

Step 1 – We prepare and submit a Non-disclosure Agreement for your review, comment and execution

Because of the nature of a relationship as “United States Agent” for any foreign device manufacturer, Oracle Consulting Group believes that a “U.S. Agent Non-disclosure Agreement” should be executed PRIOR to executing any United States Agent Agreement. The intent of this Non-disclosure Agreement is to protect each foreign device manufacturer from unwarranted disclosures of confidential and proprietary information. For the protection of each foreign device manufacturer, this Non-disclosure Agreement will remain in effect even if a subsequent United States Agent Agreement is not executed.

Oracle Consulting Group has a simple, one-page U. S. Agent Non-disclosure Agreement that can be provided by FAX to any interested firm. You will have the opportunity to review and comment on this document. Once a mutually acceptable Agreement is created it will be executed.

Oracle Consulting Group will consider executing any firm’s U. S. Agent Non-disclosure Agreement provided it does not restrict Oracle’s ability to provide our consulting services. Please FAX your firm’s Non-disclosure Agreement to 01-520-825-0556 or Email it as an attachment.

and, when requested...

Step 2 – We prepare and submit a United States Agent Agreement for your review, comment and execution

The United States Agent Agreement will be provided by FAX or as an Email attachment in MS Word and/or Adobe Acrobat electronic file formats.

You will have the opportunity to review and comment on this draft Agreement. Once a mutually acceptable Agreement is finalized, that United States Agent Agreement will be executed and, upon the receipt of the executed Agreement and payment in our offices, the contracted services will be initiated.

Each contracted client is responsible for reporting our company as its United States Agent to the U.S. Food and Drug Administration. We will provide each contracted client with all appropriate reporting information during execution of our Agreement.

FAX BACK or MAIL BACK

UNITED STATES AGENT INFORMATION REQUEST

TO: **ORACLE CONSULTING GROUP** FAX #: 520-825-0556
5398 Golder Ranch Rd., Ste. 1 VOICE #: 520-825-0555
Tucson, Arizona 85739 Email: foreignagent@fdamaze.com

- Yes, we would like to understand Oracle Consulting Group's U.S. Agent Services.
- We are interested in the **U.S. Agent Service** only.
- We are interested in the **U.S. Agent Service** and Oracle's **Company Official Correspondent Service**.
- At this time are interested in receiving a Non-disclosure Agreement only.
- Our firm's Non-disclosure Agreement is attached.
- We are interested in receiving both a Non-disclosure Agreement and a **United States Agent Agreement**.
- Please send us a copy of the revised regulation.
- Please send all materials by Email (MS Word attachments), FAX, Mail

We have _____ regulated products distributed in the U.S. Our FDA regulated products include [describe briefly]: _____

Please Print

FROM: _____
(your name, title)

FIRM NAME: _____

FIRM ADDRESS: _____

Mail Stop: _____ CITY: _____

COUNTRY: _____

PHONE COUNTRY CODE: _____

FAX # _____ VOICE # _____

Email address: _____

Firm Web Site: _____