
List of Subjects in 21 CFR Part 870

Medical devices, Cardiovascular devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

§870.3535 Intra-aortic balloon and control system.

(a) Identification. An intra-aortic balloon and control system is a prescription device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

(b) Classification. (1) Class II (special controls) when the device is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure. The special controls for this device are:

(i) Appropriate analysis and non-clinical testing must be conducted to validate electromagnetic compatibility and electrical safety of the device;

(ii) Appropriate software verification, validation, and hazard analysis must be performed;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility and shelf life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components;

(v) Non-clinical performance evaluation of the device must provide a reasonable assurance of safety and effectiveness for mechanical integrity, durability, and reliability; and

(vi) Labeling must bear all information required for the safe and effective use of the device, including a detailed summary of the device- and procedure-related complications pertinent to use of the device.

(2) Class III (premarket approval) when the device is indicated for septic shock and pulsatile flow generation.

(c) Date premaket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with FDA on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE FEDERAL REGISTER], for any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE FEDERAL REGISTER], been found to be substantially equivalent to any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976. Any other intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 12, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I


Food and Drug Administration Safety and Innovation Act Title VII—Drug Supply Chain; Standards for Admission of Imported Drugs, Registration of Commercial Importers and Good Importer Practices; Notification of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting regarding FDA’s implementation of Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA), which provides FDA with important new authorities to help it better protect the integrity of the drug supply chain. In addition to providing a general overview of Title VII and FDA’s approach to implementing these provisions, the meeting will give interested persons an opportunity to provide input that will assist FDA in the development of regulations implementing two sections of Title VII, which relate to standards for admission of imported drugs and commercial drug importers. Specifically, FDA is seeking information on the types of information that importers should be required to provide under Title VII as a condition of admission. FDA is also seeking information regarding registration requirements for commercial drug importers and good importer practices to be established under Title VII.

DATES: The public meeting will be held on July 12, 2013, from 9 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring MD 20993. Please note that visitors to the White Oak Campus must enter through Building 1. The White Oak Campus location is a Federal facility with security procedures and limited seating. There is no fee to register for the meeting and registration will be on a first come, first serve basis. Early registration is recommended because seating is limited. Onsite registration will also be permitted if there is available space. See section IV of this document, “How to Participate in
the Public Meeting,” for the date and
time of the public meeting and closing
dates for advance registration.

FOR FURTHER INFORMATION CONTACT:
Susan DoMars, Office of Global
Regulatory Operations and Policy, Food
and Drug Administration, 10903 New
Hampshire Ave., Bldg. 32, rm. 3302,
Silver Spring, MD 20993, 301–796–
4635, email: susan.demars@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The globalization of the
pharmaceutical market has created
tremendous challenges for FDA,
including dramatic increases in drug
imports, complex and fragmented global
supply chains, and increasing threats of
fraudulent and substandard drugs. Title
VII of FDASIA (Pub. L. 112–144) amends
the Federal Food, Drug, and
Cosmetic Act (the FD&C Act) to provide
FDA with important new authorities to
respond to these challenges and better
ensure the safety, effectiveness, and
quality of drugs imported into the
United States. These authorities
increase FDA’s ability to collect and
analyze data to make risk-informed
decisions, employ risk-based
approaches to facility oversight, partner
with foreign regulatory authorities to
leverage resources through information
sharing and recognition of foreign
inspections, and drive safety and quality
throughout the supply chain.

Implementation of these authorities will
significantly advance the strategies set
forth in the Pathway to Global Product
Safety and Quality report published by
FDA (available at http://www.fda.gov/
downloads/AboutFDA/centersoffices/
OfficeofGlobalRegulatoryOperationsand
Policy/GlobalProductPathway/
UCM262528.pdf), and accelerate the
Agency’s adaptation to the rapidly
changing demands of the global
environment. Implementation of these
authorities will also support and
advance FDA’s ongoing industry
oversight of quality related initiatives.

At the same time, implementation of
Title VII of FDASIA is difficult and
complex, and requires not only the
development of new regulations,
guidances, and reports, but also major
changes in FDA information systems,
processes, and policies. Since the
enactment of FDASIA in July 2012, FDA
has been working diligently to
implement the provisions of Title VII
and has prioritized these efforts based on
public health impact in order to
maximize use of the Agency’s limited
resources.

Sections 713 and 714 in Title VII of
FDASIA relate to drugs imported or
offered for import and commercial drug
importers. Section 713 allows FDA to
require, as a condition of granting
admission to a drug imported or offered for
import into the United States, that an
importer electronically submit
information demonstrating that the drug
complies with applicable requirements of
the FD&C Act. As specified in section
713, such information may include:

Information demonstrating the
regulatory status of the drug, such as the
new drug application number,
abbreviated new drug application
number, investigational new drug
number, or drug master file number;
facility information, such as proof of
registration and the unique facility
identifier; indication of compliance
with current good manufacturing
practice (CGMP), testing results,
certifications relating to satisfactory
inspections, and compliance with the
country of export regulations; and any
other information deemed necessary
and appropriate by the Secretary to
assess compliance. Section 713 also
allows FDA to take into account
differences among importers and types
of imported drugs and, based on the
level of risk posed by the imported drug,
provide for expedited clearance for
those importers that volunteer to
participate in partnership programs for
highly compliant companies and pass a
review of internal controls, including
sourcing of foreign manufacturing
inputs, and plant inspections. Section
713 requires FDA to adopt regulations
implementing section 713 not later than
18 months after the date of enactment of
FDASIA.

Section 714 requires commercial drug
importers to register with FDA and
submit a unique identifier for the
principal place of business at the time
of registration. FDA is to specify a
unique facility identifier system to be
used by registrants. Section 714 amends
section 502(o) of the FD&C Act (21
U.S.C. 352(o)) to deem misbranded a
drug imported or offered for import by
a commercial importer of drugs not duly
registered. Section 714 also requires
FDA, in consultation with the Secretary
of the Department of Homeland Security
acting through U.S. Customs and Border
Protection, to issue regulations
establishing good importer practices
that specify the measures an importer
shall take to ensure that imported drugs
are in compliance with the FD&C Act
and the Public Health Service Act.
Section 714 requires FDA to adopt
regulations implementing section 714
not later than 36 months after the date
of enactment of FDASIA.

The purpose of this document is an
opportunity for FDA to share information regarding
Title VII and the Agency’s approach to
implementation, and to obtain input
from stakeholders that will assist FDA
in developing regulations under
sections 713 and 714.

II. Purpose and Format of Meeting

The first part of the public meeting
will consist of introductory
presentations by FDA that will provide
an overview to stakeholders regarding
Title VII, including the new authorities
ganted to FDA under Title VII and their
importance in ensuring drug safety,
effectiveness, and quality; how Title VII
relates to and will help advance FDA’s
larger strategic initiatives; the Agency’s
approach to implementation; and the
progress achieved to date.

The second part of the meeting will be
used to obtain input from stakeholders
on issues relating to standards for
admission of imported drugs,
registration of commercial importers,
and good importer practices that will
assist FDA in the development of the
regulations described previously.

Individuals will have opportunities
to express their views by making
presentations at the meeting and
submitting written comments to the
dockets for these matters (see section V
of this document).

III. Scope of Public Input Requested

FDA is particularly interested in
obtaining information and public
comment on the following topics:

A. Section 713: Standards for
Admission of Imported Drugs

1. How should the regulations
implementing section 801(r) of the
FD&C Act (21 U.S.C. 381(r)), as
amended by section 713 of FDASIA,
define “importer” as that term is used in
801(r)(l)?

2. What information should FDA
require importers to submit at the
time of entry that would demonstrate a
drug’s compliance with applicable
requirements of the FD&C Act as a
condition of granting admission of the
drug into the United States?

3. What information could an
importer submit to FDA at the time of
entry to demonstrate compliance with
applicable requirements of the FD&C
Act relating to:
   a. homeopathic drugs intended for
human use,
   b. articles intended for human drug
compounding,
   c. articles intended for animal drug
compounding, and
   d. drugs intended for research?

4. What information should FDA
request from importers at the time of
entry to help assess whether a drug
complies with applicable requirements of the FD&C Act? 
5. What information could importers submit at the time of entry to demonstrate compliance with country of export regulations in accordance with section 801(r)(2)(C) of the FD&C Act? 
6. What information could importers submit at the time of entry to demonstrate that a drug offered for import complies with U.S. CGMP requirements? 
7. What information could importers submit at the time of entry that would serve as evidence of satisfactory inspection, such as by a foreign government or an agency of a foreign government? 
8. Should FDA require that importers submit certificates of analysis (COAs) to the Agency as a condition of admission under section 801(r) of the FD&C Act? If so, how could an importer demonstrate a COA’s authenticity? 
9. Section 801(r)(4)(B)(i) of the FD&C Act permits FDA, as appropriate, to consider differences among imports and types of drugs and “based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections.”
   a. What criteria should FDA use to evaluate potential participants in “voluntary partnership programs for highly compliant companies”? 
   b. How could FDA take into account differences among importers and types of drugs to allow for expedited entry as part of a voluntary partnership program? 
   c. What risk factors should FDA consider when determining drug admissibility under a voluntary partnership program? 
10. What benefits and burdens may be created by requiring drug importers to electronically submit information demonstrating that a drug complies with applicable requirements of the FD&C Act as a condition of admission? How could we minimize any possible burdens? How do we strike a reasonable balance between rigor and efficiency in requiring information that is both reliable and yet can be submitted and reviewed efficiently? 
B. Section 714: Registration of Commercial Importers of Drugs 
1. How should the regulations implementing section 714 of FDASIA (section 801(s) of the FD&C Act) define “commercial importer” to ensure that the appropriate entities are required to register with FDA and meet requirements regarding good importer practices (GIP)? Should these “commercial importers” be the same entities as the “importers” required to comply with the standards for admission to be adopted under section 801(r) of the FD&C Act? 
2. Under section 801(s)(1) of the FD&C Act, the registration regulations will apply to commercial importers of “drugs.” A “drug” is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) and includes, but is not limited to, finished dosage form drug products, drugs for further processing, active pharmaceutical ingredients, and other drug components, including inactive ingredients. Should commercial importers of certain types of drugs, such as inactive ingredients, be exempt from the commercial importer registration requirements? Should the importation of drugs for certain purposes (e.g., research use) be exempt from registration? 
3. What information should commercial importers be required to submit as part of their registration? 
4. What benefits and burdens might be created by requiring commercial drug importers to register with FDA? How can we minimize any possible burdens (e.g., through gradual implementation, exemption of certain commercial importers, use of other alternatives)? 
C. Section 714: Good Importer Practices 
1. How might FDA structure the GIP regulations to avoid imposing redundant regulatory requirements on commercial importers that also are drug manufacturers and therefore would be subject to both the GIP and CGMP requirements? 
2. Should the GIP regulations require commercial importers of drugs to establish drug safety management programs to ensure that imported drugs meet the requirements of the FD&C Act and the Public Health Service Act, as applicable? If so, what matters (e.g., procedures, personnel) should the GIP regulations require commercial importers to address in such programs? 
3. What drug safety management programs or other measures do commercial importers currently have in place to ensure that imported drugs are manufactured in compliance with applicable FDA requirements? How do these programs and measures differ for different “types” of drugs? 
4. Should the GIP regulations include qualifications and training for personnel who perform GIP activities? If so, what qualifications and training should be required? 
5. Should the GIP regulations include a requirement for commercial importers to assess whether it is appropriate to import a particular drug from a particular foreign supplier? If so, what information on the drug and the supplier should the commercial importer be required to consider as part of this assessment? 
6. Should commercial importers be required to conduct activities to verify that a drug that is offered for import is in compliance with applicable U.S. requirements (e.g., the CGMP regulations) and are not adulterated under section 501 of the FD&C Act (21 U.S.C. 351) or misbranded under section 502 of the FD&C Act? If so, what supplier verification activities should commercial importers be required to conduct? 
7. Should there be different supplier verification or other GIP requirements for different “types” of drugs? Should there be different requirements for particular types of finished dosage form drug products that might be associated with different levels of risk (e.g., sterile injectables, drugs that require temperature controls)? If so, what should these requirements be? 
8. Should the GIP regulations require commercial importers to obtain a COA for each imported drug? Should such a requirement apply only to certain types of drugs or commercial importers? If commercial importers are required to obtain COAs, should the commercial importer also be required to conduct testing to verify the accuracy of the COA? 
9. Should the GIP regulations include specific requirements for drugs imported for export in accordance with section 801(d)(3) of the FD&C Act? If so, what should these requirements be? 
10. How should the GIP regulations reflect or incorporate the requirements concerning the standards for admission of imported drugs under section 801(r) of the FD&C Act? For example, should the GIP requirements include the adoption of procedures to ensure that the commercial importer submits the compliance information required under section 801(r) and the regulations implementing that section? If so, what procedures should commercial importers be required to follow to ensure that these requirements are met? 
11. Should the GIP regulations require commercial importers to take corrective actions when the drugs they import or offer for import are not in compliance with applicable U.S. requirements? If so, what actions should importers be required to take? 
12. Should the GIP regulations include a requirement for commercial importers to list the drugs they import or offer for import? If so, what
information should be required with listing?

13. What records should commercial importers be required to maintain under the GIP regulations?

14. What other matters, if any, should the GIP regulations address?

15. How should FDA take into account “differences among importers and types of imports, including based on the level of risk posed by the imported product,” in determining reasonable time periods for commercial importers to come into compliance with the GIP regulations under section 714(d)(3) of FDASIA? In considering such differences, how should FDA determine the level of risk posed by an imported drug?

16. What benefits and burdens might be created by requiring commercial importers to comply with GIP regulations? How can we minimize any possible burdens (e.g., through gradual implementation, exemption of certain commercial importers, use of other alternatives)?

IV. How to Participate in the Public Meeting

Individuals who wish to present at the public meeting must register on or before July 5, 2013, through the FDASIA Web site at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm and provide complete contact information, including name, title, affiliation, address, email, and phone number. In section III of this document, FDA has included questions for comment. You should identify by number each question you wish to address in your presentation, provide a brief description of your presentation, and indicate the approximate desired length of your presentation, so that FDA can consider these in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation. An agenda will be posted on the FDASIA Web site at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm prior to the meeting.

Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket. See table 2 of this document for a list of docket numbers and corresponding sections of FDASIA and topics.

<table>
<thead>
<tr>
<th>Date of public meeting</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address (non-electronic)</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of public meeting</td>
<td>July 12, 2013, 9 a.m. to 5 p.m.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advance registration</td>
<td>By July 5, 2013</td>
<td><a href="http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm">http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm</a></td>
<td>FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993.</td>
<td>Onsite registration begins at 7:30 a.m.</td>
</tr>
<tr>
<td>Request special accommodations due to disability.</td>
<td>By July 5, 2013</td>
<td></td>
<td>Susan DeMars, 301–796–4635, email: <a href="mailto:susan.demars@fda.hhs.gov">susan.demars@fda.hhs.gov</a>.</td>
<td>Registration will also be accepted onsite on the day of the meeting, as space permits.</td>
</tr>
<tr>
<td>Make a request for an oral presentation and provide a brief description of the oral presentation.</td>
<td>By July 5, 2013</td>
<td><a href="http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm">http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsToTheFDCA/FDASIA/ucm20027187.htm</a>.</td>
<td></td>
<td>Requests made on the day of the meeting to make an oral presentation may be granted as time permits. Information on requests to make a presentation, including any personal information provided, may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>.</td>
</tr>
</tbody>
</table>
TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS—Continued

<table>
<thead>
<tr>
<th>Date</th>
<th>Electronic address</th>
<th>Address (non-electronic)</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit electronic or written comments.</td>
<td>By August 12, 2013 ........................................</td>
<td>Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments.</td>
<td>All comments must include the Agency name and the docket number corresponding with the section of FDASIA and topic on which you are commenting (see table 2 for a list of docket numbers and corresponding sections and topics). All received comments, including any personal information provided, may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>. FDA encourages the submission of electronic comments by using the Federal eRulemaking Portal.</td>
</tr>
</tbody>
</table>

V. Comments

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to the Federal eRulemaking Portal at http://www.regulations.gov or written comments or the Division of Dockets Management (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20857. Because multiple docket numbers are associated with this document, please include with your comments the docket number(s) that corresponds with the section of FDASIA and topic on which you are commenting (see table 2 of this document for a list of docket numbers and corresponding sections and topics).

Comments that address more than one docket must be filed with each docket to ensure consideration. The deadline for submitting comments to the docket is August 12, 2013. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

TABLE 2—DOCKET NUMBERS FOR EACH SECTION AND TOPIC

<table>
<thead>
<tr>
<th>Section of FDASIA</th>
<th>Topic</th>
<th>Docket No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>713</td>
<td>Standards for admission of imported drugs</td>
<td>FDA–2013–N–0683</td>
</tr>
<tr>
<td>714</td>
<td>Registration of commercial importers of drugs</td>
<td>FDA–2013–N–0684</td>
</tr>
<tr>
<td>714</td>
<td>Good importer practice</td>
<td>FDA–2013–N–0685</td>
</tr>
</tbody>
</table>

VI. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and http://www.regulations.gov approximately 30 days after the meeting. A transcript will also be made available in either hardcopy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: June 12, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 74

RIN 2900–A063

VA Veteran-Owned Small Business (VOSB) Verification Guidelines; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Advanced notice of proposed rulemaking; correction.

SUMMARY: In a document published in the Federal Register on May 13, 2013, the Department of Veterans Affairs (VA) amended its Veteran-Owned Small Business (VOSB) Verification Guidelines Program regulations to provide greater clarity, to streamline the program and to encourage more VOSBs to apply for verification. The preamble of that document contained several errors. This document merely corrects those errors and does not make any substantive change to the content of the advance notice of proposed rulemaking.

DATES: The comment period for the proposed rule published May 13, 2013, at 78 FR 27882, remains open until July 12, 2013.

FOR FURTHER INFORMATION CONTACT: Tom Leney, Executive Director of the Office of Small and Disadvantaged Business Utilization (00SB), Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (202) 461–4300. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The advance notice of proposed rulemaking (FR Doc. 2013–11326) that VA published on May 13, 2013, at 78 FR 27882, contained two errors—the word “advanced” was missing from the