Custom Device Exemption

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Table of Contents

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

The Food and Drug Administration (FDA) has developed this draft document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in Section 520(b) the Food, Drug and Cosmetic Act (FD&C Act). The guidance provides draft definitions of terms used in the custom device exemption, explains how FDA proposes to interpret the "5 units per year of a particular device type" language contained in section 520(b)(2)(B), describes what information FDA proposes should be submitted in a Custom Device Annual Report (annual report), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption. 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.

II. Background

Effective on July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) required the implementation of changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended an existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (not to exceed 5 units per year) qualifying for the custom device exemption; and

- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Although the revisions to the custom device exemption clarify the availability of the exemption in certain circumstances – for example, when more than one (but fewer than five) devices are manufactured per year and when modifications are made to a marketed device – the new statutory language does not create a broad, new exemption from sections 514 and 515 of the FD&C Act. Under the revised provision, as under the original custom device exemption, custom devices should represent a narrow category for which, because of the rarity of the patient's medical condition or physician's special need, requiring compliance with premarket review requirements and performance standards under sections 514 and 515 of the FD&C Act is impractical.

Historically, practitioners and manufacturers have sought custom device exemptions for devices more properly considered under a compassionate use protocol. FDA notes that some devices deemed ineligible for custom devices status prior to FDASIA would remain ineligible under the new provision, but may qualify for compassionate use. Although a full discussion of compassionate use is outside the scope of this guidance, a short discussion of compassionate use is included in the Question and Answer section of this draft guidance.

III. Definitions

Device Type
A generic device type is defined as a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness. (21 CFR 860.3(i)). For the purposes of this guidance, "device type" more specifically describes devices with common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or product code.

Importer
"Importer" means any person who imports a device into the United States.[1]

Necessarily Deviates
"Necessarily deviates" means that a device should be sufficiently unique so that clinical investigations would be impractical, and could not be performed to demonstrate conformance to applicable performance standards and/or support premarket review.[2]

Not Generally Available
A device that is "not generally available" is a device not generally available in finished form and that is not advertised by the manufacturer, importer, or distributor for manufacture and/or commercial distribution in the United States and is of a type available [for introduction into

[1] 21 CFR 806.2(f).
[2] 48 FR 248 Pages 56778, 56796, December 23, 1983.

commercial distribution] in quantities of less than five units per year. This includes, but is not limited to, devices without electronic or hard copy literature, promotional material, or testimonials available. For example, a manufacturer could make a custom device in response to an unsolicited request by a physician who specifies unique design inputs when no similar product is commercially available in the United States and clinical investigations would be impractical.

Order of a Physician

"Order of a physician" refers to the written request for a custom device made by a physician, dentist, or other specially qualified person designated by FDA regulation. In the case of a prescription device, this would include the written or electronic prescription.

Special Need

A "special need" is a need that is related to unusual anatomical features of the individual doctor, dentist or any other specially qualified person designated under regulations promulgated by the Secretary.[3]

Sufficiently Rare Condition

A "sufficiently rare condition" is a condition in a patient population in which the incidence or prevalence is so small that conducting clinical investigations on such device would be impractical.

Unique Pathology

"Unique pathology" is pathological anatomy that no other device is domestically available to treat.

Unique Physiologic Condition

A "unique physiologic condition" is one that no other device is domestically available to treat.

IV. No More Than Five Units Per Year of a Device Type

Under FDASIA, "devices" that qualify for the custom device exemption contained in section 520(b) of the FD&C Act are "limited to no more than 5 units per year of a particular device type" that otherwise meet all the requirements necessary to qualify for the custom device exemption.

FDA interprets the five units in terms of five new custom device cases per year (i.e., five new patients for the patient-focused custom device or five new physicians for the physician-focused custom device, assuming all other required elements for the custom device exemption are satisfied). The five unit limitation includes all devices provided by a manufacturer to, and remaining in the possession of, the ordering physician and/or the patient. FDA does not intend to include in the tally of five units per year any extra units that are produced for a unique case because of sizing concerns, so long as those devices not used

[3] 43 FR 20726, 20747-49, May 12, 1978; 45 FR 3732 and 3740, January 18, 1980.

for that unique case are returned to the manufacturer, and not redistributed without either valid marketing authorization or for a subsequent valid custom device case. FDA recommends that these extra units be destroyed and a signed record of the destruction be maintained in the manufacturer's device history record. For example, if four sizes of a valid custom orthopedic implant are manufactured for a specific patient's need and one device is ultimately implanted into the patient, then the remaining three sizes should be returned to the manufacturer. If these units are not returned to the manufacturer, then FDA considers four of the five total units per year to have been used for this one patient. On the other hand, if the three other units are returned to the manufacturer, only one of the five units per year will have been used to treat this patient, provided the returned devices are not redistributed without either valid marketing authorization or for use in a subsequent valid custom device case.

The devices used in the case where a patient requires multiple devices of the same type (such as bilateral conditions) requiring treatment of multiple anatomical locations within a given reporting year, will be considered one unit for the purposes of tallying the five units of a device type per year, so long as those devices not used for that unique case are returned to the manufacturer, and not redistributed without either valid marketing authorization or for use in a subsequent valid custom device case. For example, in the event valid bilateral custom joint replacement devices (such as might occur in bilateral knee replacement procedures) are required for a given patient, so long as the patient's joint replacement procedures occur in the same reporting year, and all unused product is returned to the manufacturer, FDA will consider the multiple joint replacement devices needed to treat the bilateral patient as a single unit in the tally of five units per year of a device type. If the treatment of the patient's multiple anatomical locations occur during different reporting years, each treatment will contribute one unit each to the tally for the reporting year in which the treatment occurs (so long as devices not used for that unique case are returned to the manufacturer, and not redistributed without either a valid marketing authorization or for use in a subsequent valid custom device case).

V. Questions and Answers/Examples of Custom Devices

A. What premarket and postmarket requirements are my custom device exempt from fulfilling?

Under Section 520(b) of the FD&C Act, custom devices are exempt from Premarket Approval (PMA) requirements, as well as conformance to mandatory performance standards. [4] Custom Devices are *not* exempt from any other requirements, including, but not limited to, the Quality System Regulation, including Design Controls (21 CFR Part 820); Medical Device Reporting (21 CFR Part 803); Corrections and Removals (21 CFR Part 806); and Registration and Listing (21 CFR Part 807).

[4] A device not covered by an existing marketing approval would require either a PMA or a valid exemption to the requirements to obtain PMA approval in order to introduce the device into interstate commerce. Examples of potential valid exemptions or alternatives to the PMA requirement include: (1) establishing the substantial equivalence of the new device to a valid predicate device, (2) approval of an Investigational Device Exemption (IDE) or (3) meeting all the requirements for the custom device exemption.

B. The custom device exemption describes two types of custom devices: one that is specific to the special needs of the physician's practice, and one that is specific to the patient's unique physiological/pathology needs. Can a single custom device be both unique to a physician's practice and the patient's unique needs?

No, the custom device provision allows for two different categories of custom devices to be developed. One is patient-centric and the other is physician/dentist-centric; a custom device cannot be both patient and physician/dentist-centric. A custom device made to treat a patient's sufficiently rare condition leaves the medical/dental practice with the patient, while a custom device made to satisfy a sufficiently unique special need for the physician/dentist stays with that physician/dentist for use in his/her practice.

C. Can a device subject to an IDE be a custom device?

No, a device that is currently being studied or capable of study under an IDE does not meet the definition of a custom device. Additionally, the IDE is a broad exemption under which devices used in clinical investigations that meet IDE requirements are exempt (not only) from sections 514 and 515, but also from section 502, 510, 516, 519, 510(e), 520(f) and section 721 of the FD&C Act. As discussed above, the custom device exemption is more limited; thus, there would be no reason to seek a custom device exemption for a device capable of study under an IDE. Custom devices represent a much narrower category of devices, limited to devices devised for the purpose of treating sufficiently rare conditions or rare physician needs, where conducting clinical investigations would be impractical.

D. What is the relationship between compassionate use and a custom device?

Devices that do not meet all of the elements of the custom device definition described in section 520(b) of the Act may still qualify for compassionate use. FDA provides information on how to request a compassionate use of an unapproved device in the guidance document "Guidance on IDE Policies and Procedures" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm).

"Compassionate use" of an unapproved device may occur when a device that is being tested in a clinical trial under IDE is the only option available for a patient faced with a serious condition. In cases where a sponsor seeks compassionate use of a device that does not have an approved IDE in effect, please contact the CDRH IDE Staff to discuss potential compassionate use of the device. All compassionate uses require prior FDA approval under 21 CFR 812.35(a) and this approval must be obtained before the device is used. In order to obtain Agency approval, the sponsor should submit an IDE supplement requesting approval for a protocol deviation in order to treat the patient. Please refer to the guidance listed above for more information on the compassionate use of unapproved devices.

E. Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?

Modifications to a 510(k)-cleared device that maintains the original intended use and could be clinically studied would not be considered appropriate as a custom device and should be handled in accordance with 21 CFR 807.81 and the guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)" (http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080235.htm) (i.e., submission of a new 510(k) application or documentation to the design history file explaining why the change does not require a new 510(k), as appropriate). However, if an existing 510(k)-cleared device is modified in order to treat a unique pathology or unique physiological condition, which render it incapable of clinical study, the device could potentially qualify as a custom device.

It is worth noting that FDA reviews, clears, and approves for marketing many patient-specific devices (also referred to as patient-matched devices). Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as "envelope" submissions because approval or clearance of the submission covers the entire range of specifications supported by data in the submission. The final manufacturing of these devices can be delayed until the physician provides imaging data or other information to the manufacturer to finalize the specifications of the device within the cleared or approved ranges. As a result, the device is specifically tailored for the patient. While these devices have sometimes colloquially been referred to as "customized," these devices *are not custom devices* per the requirements of the custom device exemption in the FD&C Act. Marketing applications are required for these device types because both the device and patient population can be defined and studied.

F. How are revisions and servicing of existing valid custom devices included in the total of five units of a device type per year?

A device that meets all of the requirements of section 520(b) of the FD&C Act when initially distributed will not be counted against the five units of a device per year if it has later been revised or serviced, *provided that* such revision or servicing is performed in furtherance of meeting the special needs of the person, physician, or dentist for whom the custom device was initially intended prior to such revision and/or servicing. You should contact CDRH's Office of Compliance to discuss the specifics of your situation prior to undertaking the revision or servicing of such device, as discussed herein.

G. Are pediatric devices automatically custom devices, simply because the device is for a pediatric population?

No. Pediatric patient populations may be studied just as with adult populations, and to the extent that it is possible, they should be studied so that proper labeling of a

device may be created. The proper labeling can guide users toward a better understanding of performance characteristics of the device.

H. How should I label my custom device?

Custom devices remain subject to all of the labeling requirements, such as the requirement that the labeling bear adequate directions for use, may not be false or misleading, and many other requirements related to labeling, including 21 CFR 801.1. In addition, the labeling of a custom device should include the following information: (1) a statement the device is a custom device; (2) the name of the ordering physician/dentist and patient (if applicable) that the device is intended to treat; (3) indications for use; (4) sterilization status; (5) relevant composition information (materials, components, etc.); and (6) storage conditions.[5]

I. Can I market my custom device to the general public?

No. A custom device is made as a special order at the request of a physician/dentist to be used on patients with a sufficiently rare condition or for a physician/dentist's special needs (i.e., unusual anatomical features) for no more than five units per year of a device type. Section 520(b)(1)(C) sets forth that a custom device is not, among other things, made generally available in finished form through labeling or advertising.

J. What are some examples of devices that are potential custom devices?[6]

A possible example of a custom device might be one manufactured for a patient with skeletal dysplasia requiring a total hip replacement procedure to treat her osteoarthritis. The patient's skeletal dysplasia could be characterized by abnormalities in the growth and/or remodeling of cartilage and bone, resulting in short stature and angular and torsional deformities of the patient's hip. In this particular case it is possible that the patient's unique pathological anatomy might not be successfully treated with the currently available total hip replacement devices marketed in the United States. Other elements of the custom device exemption would need to be met, such as the patient population being too small to support a clinical study.

Another possible example of a custom device might be an artificial cervical disc replacement for reconstruction of the cervical disc following cervical discectomy for treatment of cervical radiculopathy in a 7'2" male patient. Under this hypothetical scenario, the osseous dimensions of this patient's cervical spine are such that the dimensions exceed those which would be accommodated by a cervical disc available

[5] For additional information on device labeling, refer to 21 CFR Part 801 and "Guidance on Medical Device Patient Labeling" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm).

[6] This is not intended to be an exhaustive list of devices that might satisfy the custom device exemption, and it represents only a subset of the information needed to meet the statutory requirements for a valid custom device. If you have questions as to whether your scenario might satisfy the custom device exemption, we encourage you to contact CDRH's Office of Compliance to discuss.

in the United States and the patient represents a population which, at this time, appears to be too small to support a clinical study.

An additional example of a possible custom device might be one manufactured for a toddler needing occipital condyle screws after surviving a severe car accident, leaving her paralyzed from the neck down and in need of instrumentation that would help hold her head up. Her physician concludes that an occiput to C2 posterior cervical fusion would be best for the patient. In the United States, there are no cleared or approved screws for placement in the occipital condyle available in the sizes needed for this pediatric patient population. At this time the pediatric patient population needing posterior occipital condyle fusion within the size range needed for the toddler could be too small to support a clinical study. This scenario might satisfy the custom device exemption, and the physician should request custom occipitocervical implants for non-standard, pediatric sized screws for use in the occiput, cervical spine, and upper thoracic spine of this specific patient.

K. What are some examples of a device that is not a custom device?

A primary total knee replacement (TKR) patient received company X's TKR device. Later, the patient needs a revision of one side of the TKR joint replacement, and could have this accomplished by utilizing company X's off-the-shelf component for revision surgeries. However, the hospital where the patient's doctor practices only uses company Y's products. The doctor would like to request a custom company Y component be made to replace the patient's failing company X component. This situation would not satisfy the requirements for a custom device exemption because a device is available domestically that could be used to treat the patient. See Section 520(b)(1)(D) of the FD&C Act.

VI. Annual Report

The statutory amendments to the custom device exemption under FDASIA added a new reporting requirement:

"… the manufacturer of such [custom]device notifies the Secretary on an annual basis, in a manner to be prescribed by the Secretary, of the manufacture of such device."

The manufacturer of the custom device must report to FDA annually, as required by section 520(b)(2)(C) of the FD&C Act, on the custom devices it supplied. The annual report should include the number of patients who received a new device or revisions of a previous custom device. Additionally, multiple custom devices or components used in one patient should be accounted for in the annual report. As noted in Section III of this guidance, typically only new custom devices will be counted toward the maximum amount of five units per year of a particular device type. However, revisions to an existing custom device should be accounted for in the annual report. In addition, the number of custom devices both provided to, and returned by, physicians or dentists to accommodate unusual anatomical features of the individual patient, physician or dentist should be accounted for in the annual report.

The annual report should summarize the number of custom devices manufactured and distributed in the United States during a 1-year reporting period. Each annual report should cover a given calendar year. The first report should contain retrospective information on custom devices provided by manufacturers from the date of enactment of FDASIA (on July 9, 2012) to the date of the first report. For all subsequent reporting periods, the report should be submitted to FDA within the first quarter of the following calendar year (e.g., by no later than March 31.). FDA will not enforce the new annual reporting requirement until the end of the calendar year following publication of the final guidance; however, FDA encourages manufacturers to submit the information required by the statute in any format in advance of the finalized guidance being published.

A complete annual report should include all of the information as set forth below. FDA believes it can review a complete annual report more efficiently and may be less likely to request additional information. The following sections provide guidance on how to submit the annual notification (e.g., the annual report) to FDA and the content of that report for both patient-centric and physician-centric custom devices.

A. Annual Report – General Contents

The following general information should be included in both patient-centric and physician-centric annual reports.

1. Cover Letter

Your report should include a cover letter that clearly states that the reason for the submission is a "Custom Device Annual Report" in the reference line. The cover letter should contain your complete contact information (i.e., the company name, address, URL, contact person, title, phone number, fax number, and email address). In addition to describing the reason for the submission in the reference line, the cover letter should also clearly identify the name of the custom devices and include the signature of the contact person or other responsible party within the company. The cover letter should also specify the reporting period (i.e., the dates the reporting period begins and ends).

2. Certification Statement

Your report should include a signed Custom Device Annual Report Truthful and Accurate certification statement that indicates that the submitter is an authorized representative for the manufacturer and that all the information provided in the paper and electronic copies of the Custom Device Annual Report is truthful and accurate to the best of your knowledge and that no material fact has been omitted. See Appendix II for a copy of the statement certificate.

3. Other Logistical Information

Your Custom Device Annual Report should be written in the English language. Any material provided in a foreign language should be accompanied by an accurate and complete English translation. You should send two copies of your Custom Device Annual Report to the address below.

We strongly encourage that one or both of your copies be an electronic copy, which can be e-mailed to customdevices@fda.hhs.gov.

Attn: Custom Device Annual Report Submission Coordinator
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
WO66, Room 2654
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

B. Annual Report -- Patient-Centric Custom Device Information

As described in Section IV of this guidance, a custom device is either patient-centric or physician/dentist-centric, but not both. In addition to the requested elements listed in Section V.A. (above) the following elements should be provided to FDA in a Custom Device Annual Report for patient-centric devices to ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

1. Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act

In your report, you should include a justification for how or why the device manufactured to treat an individual patient meets each of the following conditions contained in the FD&C Act[7]:

a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met, you should provide an explanation of why the device necessarily deviates from the premarket requirements including treating a sufficiently rare condition such that conducting clinical investigations are impractical. You may include information on the incidence or prevalence of the condition or disease the device is intended to diagnosis, treat, mitigate, prevent, or cure or is otherwise intended to affect the structure or any function of the body of man. References for the data provided should also be included. If the incidence or prevalence material referenced is not available in the published literature, you should include a copy of the reference in the annual report. If you believe that information on the incidence or prevalence of the condition or disease is not available, please provide an explanation why you believe the information is not available.

b) In order to explain how section 520(b)(1)(A) is met, you should indicate whether the device is a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician or dentist.

c) In order to explain how section 520(b)(1)(C) is met, you should attest that the device is not generally available in the United States in finished

[7] See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution.

d) In order to explain how part of section 520(b)(1)(D) and section 520(b)(2)(B) are met, you should provide a complete description of the device including device type (e.g., product code and classification regulation, as applicable), as well as the patient's unique pathology or physiological condition the device was designed to treat.

e) In order to show that section 520(b)(1)(D) is met, you should provide a statement that no other device is domestically available to treat the patient's unique pathology or physiological condition. You should maintain records of the evaluation that you used to determine that no other device is domestically available to treat the patient's unique pathology or physiological condition.

f) In order to explain how section 520(b)(1)(E)(ii) is met, you should provide the name of the individual patient in the physician's or dentist's order.

g) In order to explain how section 520(b)(1)(F) is met, you should state whether the device is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals. Additionally, you should explain under section 520(b)(1)(G) whether the device or device components have common, standardized design characteristics, chemical and material compositions, and the same manufacturing processes as commercially distributed devices.

2. Summary of Custom Devices Shipped, Used, and Returned

You should provide an annual summary of all the custom devices supplied, used, and returned during the reporting period. This includes a name or description of the device, the classification regulation (if applicable), and product code (if available). This summary should also include information on the number of each type of device that was shipped, used/remaining with the patient (e.g., implanted) in new and revision patients, and the number of custom devices that were returned to the manufacturer/distributor. In order to facilitate FDA's review of your summary report, we recommend using the format described in Table 1 of Appendix I for reporting this information.

3. Details on Custom Device Use

You should provide the following detailed information on custom devices manufactured during the reporting period.

a) Patient Information. You should indicate the total number of patients receiving custom devices. This should be broken down into patients receiving a new device, and those undergoing revisions of previously existing custom devices. Additional information on the patients should also be provided. This includes patient identifiers (e.g., initials/name and age), date of the procedure or implant, and a description of the condition

that necessitated use of a custom device.

b) Physician information. You should provide the name, address, and other contact information for the treating physician for each patient procedure.

c) Custom device or custom device components. For each custom device or device component remaining with the patient, you should provide details on each device or device component. These details should include the product name, brand name, product model number, product catalog number, other product identifier information, product code, and product classification regulation.

In order to facilitate FDA's review of your detailed custom device report, FDA recommends the format described in Table 2 in Appendix I for presenting patient, physician, and device information.

C. Annual Report –Physician or Dentist-Centric Custom Device Information

As described in Section IV of this guidance, a custom device is either considered to be patient-centric or physician/dentist-centric, but not both. In addition to the requested elements listed in Section V.A. (above) the following elements should be provided to FDA in a Custom Device Annual Report for a physician-centric device to ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

1. Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act

In your report, you should include a justification for how or why the device manufactured meets the special needs of a doctor or dentist in the course of his/her professional practice and satisfies each of the following conditions contained in the FD&C Act[8]:

a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met, you should provide an explanation of why the device necessarily deviates from the premarket requirements including addressing a sufficiently rare condition such that conducting clinical investigations are impractical. You may include information on the incidence or prevalence of the condition or disease the device is intended to diagnose, treat, mitigate, or prevent**.** References for the data provided should be included. If the incidence or prevalence material referenced is not available in the published literature, you should include a copy of the reference in the annual report. In addition, you should include an explanation of why conducting clinical investigations on such device would be impractical. If you believe that information on the incidence or prevalence of the condition or disease is not available, please identify why you believe the information is not available.

[8] See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

b) In order to explain how section 520(b)(1)(A) is met, you should indicate if the device was a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician or dentist, as well as the name of the individual doctor or dentist in the order.

c) In order to explain how section 520(b)(1)(C) is met, you should attest that the device is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution.

d) In order to explain how part of section 520(b)(1)(D) and section 520(b)(2)(B) are met, you should provide a complete description of the device including device type (i.e., product code and classification regulation as applicable), as well as the doctor's or the dentist's special need that the device was designed to meet.

e) In order to show that sections 520(b)(1)(D) and 520(b)(1)(E)(i) are met, you should provide a statement that no other device is domestically available to address the doctor's or dentist's special need in the course of conducting his/her practice. You should maintain records of the evaluation that you used to determine that no other device is domestically available to address the doctor's or dentist's special needs are met.

f) In order to explain how section 520(b)(1)(F) is met, you should provide an explanation if the device was assembled from components or manufactured and finished on a case-by-case basis to accommodate the special needs of individuals described above. Additionally, you should explain under section 520(b)(1)(G) whether the device or device components have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

2. Accommodating a Doctor's or Dentist's Special Need

You should provide an annual summary of all the custom devices both supplied to, and returned by, a physician or dentist to accommodate a special need. This information should include the name or description of the device, classification regulation, and product code (if available). This summary should also include information on the number of each type of device that was shipped/used during the reporting period and the number of custom devices that were returned to the manufacturer/distributor. In order to facilitate FDA's review of your summary custom device report, we recommend the format described in Table 1 in Appendix I for reporting this information.

3. Details on Custom Device Use

You should provide the following detailed information on custom devices distributed during the reporting period:

a) Physician information. You should provide the name, address, and other contact information for the doctor or dentist ordering the custom

device.

b) Custom device or custom device components. You should provide information on the number of custom devices or custom device components that were shipped, sold, and returned during the reporting period. This includes the product name, brand name, product model number, product catalog number, other product identifier information, product code, and product classification regulation.

In order to facilitate FDA's review of your detailed custom device report, FDA recommends the format described in Table 3 in Appendix I for presenting physician and device information.

D. FDA's Review of Your Annual Report

FDA's review of annual reports allow the agency to assess several important issues related to the manufacture and distribution of custom devices. These issues include the adequacy of report documentation and fulfillment of the requirements of section 520(b) of the FD&C Act. If we find that the information provided in your annual report is insufficient to allow a complete review, we may request additional information by letter, telephone, or e-mail.[9] If we only need clarification of an issue, we may communicate on such issues via telephone or e-mail, whichever we believe will be the most efficient.

VII. Complete Text of Section 520(b) of the Food, Drug and Cosmetic Act

Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of

[9] The FD&C Act now requires that custom device manufacturers submit annual reports for all devices distributed under the custom device exemption. Without submission of the required annual report to FDA, any devices distributed as "custom devices" would not be exempted from any applicable premarket requirements.

such physician or dentist (or other specially qualified person so designated); or (ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

Please see Appendix III for a flow diagram of the decision tree needed to implement the custom device provisions in the FD&C Act.

Appendix I
Format for Summary Data Tables

Table 1. Summary of Custom Devices Shipped, Used and Returned

Custom Device Name	**Product Code**	**Number Shipped**	**Number of New Cases Patient-Centric or Physician-Centric (as applicable)**	**Number of Revision Cases (Patient-Centric or Physician-Centric)**	**Number Returned**

Table 2. Patient-Centric Devices - Summary of Patient, Physician and Device Information for Patient-Centric Devices

Patient Identifiers	**Date of procedure/ implant**	**Description of the condition that necessitated use of a custom device and alternative treatments**	**Name and address of physician**	**Custom device name or custom device components**	**Other relevant Information**
				Product name, Brand name, Product model number, Product catalog number Other product identifier information Product code, Product classification regulation, Material composition	

710 Table 3. Physician or Dentist-Centric Devices - Summary of Physician, Dentist and Device Information

Physician name, degree and address	**Date(s) of procedures**	**Description of special need necessitating custom device**	**Custom device name or custom device components**	**Other relevant information**
			Product name, Brand name, Product model number, Product catalog number, Other product identifier information, Product code, Product classification regulation, Material composition	

711

Appendix II

Custom Device Annual Report Truthful And Accurate Statement

I certify that, in my capacity as (*the position held in company*) of

*(*company name), I believe to the best of my knowledge, that all data

and information submitted in the custom device annual report are truthful and

accurate and that no material fact has been omitted.

_____

(Signature)

_____

(Typed Name)

_____

(Date)

Appendix III
Custom Device Decision Tree

Note the term physician in the decision tree stands for physician, dentist or specially qualified person as noted in Section 520(b) of the FD&C Act.