

FDA Webinar: Custom Device Annual Reporting
Moderator: Irene Aihie
February 27, 2018
3:00 pm ET

Coordinator: Welcome and thank you for standing by. All participants will be able to listen only until the question and answer portion of today's conference. To ask a question, please press Star 1.

Today's conference is being recorded. If you have any objections, please disconnect at this time. I would now like to turn your conference over to Ms. Irene Aihie. Miss, you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education.

The Custom Device Exemption allows medical device manufacturers to market certain devices designed to treat a unique pathology or physiological condition without premarket approval. A device that meets the criteria for a custom device is exempt from Premarket Approval (PMA) requirements and conformance to mandatory performance standards. Manufacturers of custom devices must report to the FDA annually, and annual reports are due to the FDA no later than March 31 of the following year.

Today, Kareem Burney and Jamie Kamon-Brancazio will discuss and answer questions about the custom device annual report requirement. This webinar is

an opportunity for impacted stakeholders to obtain clarity on the FDA's expectations for the content of custom device annual reports to ensure completeness in meeting the reporting obligation.

Following the presentation, we will open the line for your questions related to information provided during the presentation. Additionally, there are other Center subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you Kareem...

(Kareem Burney): Good afternoon everybody. My name is Kareem Burney. I am the jurisdictional officer from the Office of Compliance. I, along with (Jamie), the consumer safety officer from the Office of Compliance, will be discussing the custom device exemption annual report.

This is the (unintelligible) of today's presentation. Please note that we will not be talking about the guidance document proper now definitions within the guidance document.

We will only be talking about operations of annual reports review so far and how to improve the quality of the annual reports to help facilitate and improve the custom device annual report review process for both industry and the FDA.

Before we begin our how to improve the annual reports, we first need to go over the middle period and outline of the report. Some of the annual reports submitted lack this information and we would like to help you get these reports reviewed as quickly as possible without having to ask for basic information.

The point of this particular slide is to emphasize specifically the filing period for annual reports. We state this because we have received some reports after the March 31 deadline and receiving an annual report after the March 31 deadline can increase the likelihood of the report not being reviewed by the FDA.

Annual reports should begin with this information. It helps us determine who to contact. Some of the annual reports received did not provide this information and, therefore, made it difficult for us to contact the firm if we needed questions answered.

Annual reports need to provide the main section distribution information in a clear, concise format, making clear what was distributed, returned and destroyed.

Some of this information was not presented in some of the annual reports we reviewed during the past year. And, again, to help facilitate the review of these annual reports quickly, we need this information in order to come to a similar determination that these devices are, in fact, custom devices.

So far, we have received only patient-centric custom device (out of) those reports. If you have questions about the physician-centric (avert) custom devices, we can address them at another time.

But for patient-centric custom devices, the following information should be provided with justification to the FDA. As you think about how to put these sections of the annual report together, think about documents that answer how is this or why is that and so on.

In the case of this slide, how is this condition a rare condition? And think about providing documents that support that basic question. For this slide, we are simply looking for information whether the device is a new product or modified product and documentation showing that this product is not available in the United States through labeling or advertising.

Many of the Avnet reports do not provide labeling or advertising information and, therefore, only provided a statement saying that this product is not available within the United States.

And for this particular slide, we need labeling and advertising information to support that particular premise. In some of the annual reports, it was not clear whether the device was – what the device was and the pathology of the patient's physical condition.

The lack of this information can delay the review. As you put together these reports, remember to provide this information. Many of the reports force us to try to go back to the firm in order to get this information.

And, again, the point of the annual report review process is to do it quickly and effectively and this information will help facilitate that process. We feel that this slide is straightforward. Just remember to provide information on how - the device or the symbol and information about the components of the device in a clear, concise manner.

And now I will hand it over to (Jamie) to discuss the annual report submission observation.

(Jamie Kamon-Brancazio): Thank you, Kareem. As Kareem just stated and just to reiterate what the FDA is looking for in these annual reports, I just wanted to go over the common inconsistencies that we've reviewed over the time period in 2017.

Listed below, you'll see some of the inconsistencies that we listed that really impact our review of the submission. Just to name a few, such as the name of the device, the indications and the intended use.

Again, all of this information is considered necessary to complete an efficient clinical review. Additionally, to ensure that the annual reports are of high quality and comprehensive, please provide documentation evidence to support statements made in the annual report.

This information or supporting documentation can be in the form of published studies, Web-based searches or professional society pages, just to list a few. And that, I believe, will be what we need in order to make a comprehensive review of the submission.

(Kareem Burney): We need this information because high quality annual reports help us learn how industry is interpreting and applying the custom device exemption. This helps to determine how to improve the program via the guidance document and review process.

It also helps us to respond to inquiries from our stakeholders such as Congress. And to summarize, remember that we need you to help us (move forward) in the custom device exemption program with these annual reports and to put together substantial and custom device annual reports that will allow us to further improve the custom device program. And now we will take any questions.

Coordinator: Thank you. If you would like to ask your question, please press Star 1 and you will be prompted to record your first and your last name. Please unmute your phone when recording your name. And to withdraw your question, press Star 2. One moment, please.

(Kareem Burney): Before we (listen to) any questions, we would just like to reemphasize the common question that we get is about the (unintelligible) submissions within the guidance document.

And just to reiterate, this presentation is not about the definitions within the guidance document. This presentation is only to address how to put together annual reports that will allow the FDA to review them effectively.

If you have any questions about the definitions within the guidance document, we can only refer you to the guidance document at this particular time.

Coordinator: And once again, please press Star 1 to ask a question. One moment.

(Jamie Kamon-Brancazio): And a quick note to our participants, we are only taking questions via the phone.

Coordinator: We have a couple questions. One moment.

(Jamie Kamon-Brancazio): Thank you.

Coordinator: Our first question comes from (Sharla). Your line is open.

(Sharla): Yes, my question is, how the (officer) can submit the annual report today. Is that by email or is it electronic? How is the process?

(Jamie Kamon-Brancazio): One second while we get that answer for you.

(Sharla): Thank you.

(Kareem Burney): At this current time, manufacturers can send their reports to the (Vision) Analyst and Program Operations, Office of Compliance, Center for Devices and Radiological Health, US Food and Drug Administration (unintelligible) 66, Room 2622. We would like for them to be in a hard and electronic copies.

(Sharla): Okay, thank you.

(Jamie Kamon-Brancazio): Operator, we'll take our next question.

Coordinator: (Suzanna Brooks), your line is open.

(Suzanna Brooks): Thank you. I just would like a little clarification about what is considered a custom device. We import toothbrushes.

(Jamie Kamon-Brancazio): One second while we get that question for you (rather). Thank you so much for your question. However, that question is actually out of the scope of today's Webinar.

But if you could please send that question to Customdevices@FDA.HHS.gov and someone will – a member of that team will get back to you.

(Suzanna Brooks): Okay, I'll do that. Thank you.

(Jamie Kamon-Brancazio): Thank you. We'll take our next question.

Coordinator: (Margaret Clipper), your line is open.

(Margaret Clipper): Hi. Can you give us an estimate of the amount of time it will take for us today to review the annual report? And is feedback provided once the review is completed?

(Jamie Kamon-Brancazio): If you could actually send that question to Customdevices@FDA.HHS.gov so that we can give you a more detailed timeframe. But we can't give that – we can't give you a timeframe right now. But if you send that to that email address then we'll get back to you.

(Margaret Clipper): Okay, great. Thank you very much.

(Jamie Kamon-Brancazio): All right, thank you.

Coordinator: Once again, to ask a question, please press Star 1. Okay, I have no further questions. I would now like to turn your conference back to Ms. Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the (CBRH) Webpage at [www.fda.gov/training/\(cbrh\)learn](http://www.fda.gov/training/(cbrh)learn) on Wednesday, March 7.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback.

Following the conclusion of today's Webinar, please complete a short (18) question survey about your FDA (CBRH) Webinar experience. This survey can be found at FDA.gov/webinar immediately following the conclusion of

today's live Webinar. Again, thank you for participating and this concludes today's Webinar.

Coordinator: Thank you for your participation. You may disconnect at this time.

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