FDA Webinar: Acceptance Review for De Novo Classification Requests: Final Guidance
Moderator: Irene Aihie
September 18, 2019
11:00 am ET

Operator: Good morning, everybody. Thank you all for standing by. I'd like to inform all participants that your lines have been placed in a listen only mode until the question and answer session of today's call. Today's call is also being recorded if anyone has any objections to that they may disconnect at this time. I'd like to now turn the call over to Ms. Irene Aihie. Thank you, ma'am and you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie, at CDRH's Office of Communication and Education. On September 5, 2019, the FDA issued the final guidance document, Acceptance Review for De Novo Classification Requests. The guidance explains the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class designation meets a minimum threshold of acceptability and should be accepted for substantive review.

Today, Sergio de del Castillo, De Novo Program Lead in the Office of Regulatory Program here in CDRH will present an overview of the guidance document. Following the presentation, we will open the line for your questions related to the information provided during the presentation.

Additionally, there are other center subject matter experts here with us to assist with the Q&A portion of our webinar. Now I give you Sergio.

Sergio de del Castillo: Thank you, Irene, and welcome to everyone joining us today. What I'm going to cover today are the objectives for today's webinar and provide some background that explains and provides context for the final guidance that is the subject of today's webinar. I'll provide a summary of the final De Novo RTA guidance and explain the transition period that's currently in effect for the guidance. I'll end with a listing of resources that are available to you during the De Novo RTA process and RTA review, and then at the end we'll take questions.

After the completion of today's webinar, we hope that you will be able to understand the acceptance or RTA review policy and process for original De Novo requests. You should also be able to identify the required content elements which are necessary for acceptance of an original De Novo and finally you should be able to identify and explain the various actions that we may take during the RTA review process and their impacts on the review clock.

During the presentation I'll be using the acronym RTA -- which stands for refuse to accept -- quite a few times, and I'll be using this interchangeably with the word acceptance. For example, I will also use acceptance review and RTA review interchangeably. I'll also be using shorthand titles for some of the titles of the guidance documents that we're discussing today. For example, for the final guidance “Acceptance Review for De Novo Classification Requests,” I'll refer to this as simply “De Novo RTA Guidance.”

In 2017, Congress enacted the FDA Reauthorization Act, also known as FDARA. And as part of that, that included the Medical Device User Fee

Amendments of 2017, also known as MDUFA IV. In our negotiations with representatives from the medical device industry, for the first time we agreed to performance goals for De Novo classification requests based on the timeliness of the review.

To facilitate a more efficient and timely review and ensure that we meet these new performance goals, we committed to developing draft and final guidance that includes a, quote unquote, submission checklist. In other words, we committed to developing an RTA acceptance review and policy. The draft of this guidance was issued on October 30 of 2017, and the final guidance -- which we'll be discussing today -- was published last week on Monday, September 8, 2019.

I'll now provide a summary of the final de novo RTA guidance. The goal of this guidance is to ensure that original De Novo requests contain sufficient information in order for us to accept it and begin the substantive review process. The guidance identifies the content that we believe is necessary in order for us to accept an original De Novo. As I mentioned, this guidance honors our MDUFA IV commitment to develop a quote unquote submission checklist and help facilitate an efficient and timely review to meet our new performance goals.

For those of you with experience in the RTA review of a 510(k) or PMA, much of the information in the guidance and information I'll be presenting today should look very familiar to you. The De Novo RTA policy and process was modeled after the 510(k) and PMA programs. And finally as a note that the final guidance is not very different from the draft that we issued a couple years ago. There are just a few minor changes that are not relevant to today's training.

One unique feature of the guidance is that there are two checklists included in the appendices of the document. Appendix A contains the acceptance or RTA checklist. This is the checklist that identifies all of the content elements that we believe are necessary in order for us to accept an original De Novo request and begin substantive review. This includes things such as identification of the intended use of the subject device, a device description, and -- if recommending Class II -- proposed special controls. It is this checklist that will be used by the lead reviewer during the RTA review to determine whether or not the file can be accepted for substantive review.

In Appendix B, we've also included another checklist entitled Recommended Content Checklist. As the name suggests, this information isn't required but we do provide it to you as an additional resource for consideration in developing the content of a De Novo. Many of the items that are listed in Appendix B are items that would typically be identified as deficiencies either through interactive review or formal letters to the requester. Examples of these types of elements are identification of prior submissions for the same device, the classification summary or eligibility analysis, and draft device labeling.

While both of these checklists are available to you in helping you to develop the content of your De Novo, the recommended contact checklist in Appendix B will not be used to conduct RTA reviews. Only the RTA checklist in Appendix A will be used by the lead reviewer to conduct the RTA review.

As a result of this new step in the review process, we've also included updates to two other relevant guidance documents. The first is the De Novo Actions/Clock Guidance and it identifies the various actions that the agency can take during the RTA review, as well as the requester's actions, and explains how each of these actions impacts the review clock. We've also updated the De Novo User Fees Guidance to explain the criteria for requesting

a user fee refund if a De Novo is withdrawn before it is accepted for review. The guidance continues to explain how to request user fee refunds where appropriate.

I'd now like to provide an overview of the De Novo RTA policy and review process. Again, if you have experience with the RTA review of a 510(k) or PMA, this will look virtually identical. Again, the goal here is to determine if the De Novo request is administratively complete and contains sufficient information based on the acceptance checklist in Appendix A of the guidance. This is not intended to be a substance review. Rather, we're simply looking to determine if those content elements are present so that we may begin the substantive review.

We intend to complete the RTA review within 15 calendar days of receiving an original De Novo request. If the RTA review is not completed within fifteen calendar days, the De Novo will be considered automatically accepted and we will immediately proceed into the substantive review phase. In this scenario -- if the RTA review is not completed within the 15 calendar days and is considered automatically accepted -- the requester will be notified by email.

Now I want to go over the two decisions that can be made on a De Novo request during the RTA review. The first is a refuse to accept or RTA decision. This decision means that we determined that the De Novo is incomplete, meaning that it has not included all of the content elements in the RTA checklist in Appendix A of the guidance and we cannot begin the substantive review.

If this decision is made, we will notify the requester by email that the De Novo is not accepted, and we will identify the items that are missing and must

be provided in order for us to be able to accept the file. As a note, the email will include an attachment, which is a copy of the RTA checklist as completed by the lead reviewer, so you may know for certain which items exactly are missing and need to be provided.

When the De Novo is determined to be incomplete -- that is, an RTA decision is made -- the De Novo is placed on hold and the review clock is reset to Day 0. Once the De Novo is placed on hold, the requester has 180 days to provide the missing elements as identified in the email.

The other decision that we might make is to accept the De Novo request. This means the De Novo is administratively complete. It contains all the required content elements, and we may begin the substantive review phase. Also in this situation, FDA will email the requester to notify them that the De Novo has been accepted for review, and the substantive review begins. The review clock will continue from the date of the original submission or the date of submission of missing elements if it was previously refused to accept.

So on September 8, we published the final version the De Novo RTA Guidance, as well as the updates to the De Novo Actions/Clock Guidance and De Novo User Fees Guidance that I summarized previously. We have committed to a 60-day transition period in order for FDA and industry to operationalize this new policy and process.

During the 60-day transition period -- that is between September 8 through November 7 of this year -- we intend to continue to accept all original De Novo requests that are submitted to the center. During the transition period, we will not be conducting formal RTA reviews. Beginning on November 8, we will begin formal RTA reviews for any new original De Novo requests received on this date or any time thereafter. If a De Novo is received prior to

November 8, we do not intend to conduct an RTA review, and it will be accepted as is.

Here are resources that are available to you during the entirety of the review process, including the RTA review. As a note on the first bullet here, there's a link to the De Novo page within CDRH Device Advice. This is a nice one--stop-shop for lots of different information that may be helpful to you during the review process. It includes links to all the guidance documents I mentioned today, as well as other guidance and resources that may be helpful to you.

And that concludes the presentation for today. In just a moment we'll be able to take any questions that you may have. While we're preparing for the question and answer session, I do want to reiterate a few important points.

One, we are currently in a 60-day transition period for the guidance. During the transition period we will not be conducting RTA reviews of original De Novo requests. Anything that is submitted between now and November 7 will continue to be accepted per existing process. Also on November 8, we will begin formal RTA reviews for any De Novos received on that date or thereafter.

Irene Aihie: Thank you, Sergio. And we'll now take questions from our callers on the line.

Operator: To ask a question, please press star followed by 1 and record your name when prompted. Your name is required to introduce your question. Again, that is star followed by 1. Ad I will let you know when questions begin. Our first question comes from Ms. (Allison Colmiama). Ma'am, your line is now open.

(Allison Komiyama): Thanks, Sergio, thanks so much for the great presentation. I just had a quick question about the - if you are RTA and you have - you believe that some of the questions are actually items that should be part of the substantive review, what would be the best process to either communicate with the De Novo Staff or your lead reviewer to figure out if those can be pushed to after the RTA process?

Sergio de del Castillo: So if you believe that any element that's identified in the RTA decision is actually not appropriate for the RTA review -- meaning that it should be something that's discussed or identified during the substantive review -- it would be appropriate to reach out first to the lead reviewer to clarify why that was identified as a reason for the RTA decision and if necessary you can reach out to the De Novo Staff or Program.

(Allison Colmiama): Great, thank you.

Sergio de del Castillo: You're welcome.

Operator: Our next question comes from (Dan Adams). Sir, your line is now open.

(Dan Adams): Just a quick question the transition period. Does that also apply to pre-De Novo - or De Novo pre-submission requests?

Sergio de del Castillo: No this is only applicable…

(Dan Adams): The formal De Novo?

Sergio de del Castillo: …original De Novo requests. The pre-submission process is something entirely separate.

(Dan Adams): Okay, right, that's what I thought. Thank you.

Sergio de del Castillo: Sure.

Operator: Again, to ask a question please press star followed by 1 and record your name when prompted. One moment for any other questions. I see no further questions at this time.

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 CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Thursday, September 26. 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 live webinar, please complete a short 13-question survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/cdrhwebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating. This concludes today's webinar.

Operator: And that concludes today's call. Thank you all for participating. You may now disconnect.

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