NWX-HHS FDA

Moderator: Irene Aihie
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1:30 pm CT

Coordinator: Welcome, and thanks for standing by. At this time participants are in a listen-only mode until the question and answer session of today's call. At that time, you may press Star 1 to ask a question.

Also, at this time I would like to inform all parties that today's call is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the call over to Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I'm Irene Aihie, of CDRH's Office of Communication and Education. Today's webinar will focus on the final order that requires manufacturers of automated external defibrillators, AEDs, to submit premarket approval applications, PMAs, in order to market their products. This order applies to both the manufacturers of AEDs, as well as those companies that manufacture accessories to these products.

Today, Linda Ricci, from the Office of Device Evaluation here in CDRH, will present an overview of the final order and clarify what it means for manufacturers. Following Linda's presentation, we will open the line for

questions. To assist Linda with the Q&A portion are other subject matter experts from CDRH.

Now, I give you Linda…

(Linda): Good afternoon. My name is (Linda Ricci) and I work in the office of device evaluation in the Center for Devices and Radiological Health.

Today's webinar is intended to provide an overview of the final order, with a primary focus on what is expected as stated in the final order from manufacturers of these devices in terms of the timeline for submitting PMA.

Today's webinar will cover the following items: 1. An overview of the final order. 2. A discussion of the timeline for submitting PMA's for new devices or new accessories. 3. A discussion of the timeline for submitting PMA's for AED devices that are currently distributed. 4. A discussion of the timeline for submitting PMA's for AED accessories that are currently distributed. And lastly, what we envision as the next step for manufacturers.

The Food and Drug Administration is issuing a final order to require the filing of premarket approval applications, or PMA's, for automated external defibrillator systems, which consist of an AED, and those AED accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock.

The final order can be found at the link provided on this slide. The order covers both the AED device itself and all accessories that are necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock. Examples of these accessories include pad electrodes, batteries, adaptors, and hardware keys for pediatric use.

So what does a final order mean? Basically, it means the devices or accessories that have not received a 510(k) clearance will need to receive a PMA approval prior to beginning distribution.

AED devices which have received a 510(k) clearance may continue to be distributed as long as the device is included in an intent to file, and subsequent PMA within the time frame that will be discussed in the following slides.

AED accessories that have received the 510(k) clearance may also continue to be distributed, as long as they are included in a PMA within the timeframe laid out in the order.

Just to be clear, devices or accessories for which a 510(k) clearance was not issued, must receive a PMA approval before the device can be legally marketed. This applies to both the devices and the accessories.

The intent to file is a mechanism by which a manufacturer of a currently marketed AED device can indicate to the agency which devices or device the manufacturer intends to include in the PMA. The manufacturer can continue to distribute devices that are included in an intent to file until the PMA is submitted, but no longer than 18 months. The intent to file must be formally submitted to the agency within 90 days, from the date of the final order publication -- this would be around May 4, 2015 -- and it must include a list of all devices, including model numbers and 510(k) numbers for which a PMA will be sought.

Any currently marketed device which is not included in the intent to file must cease to be distributed as of May 4, 2015. As a reminder, the intent to file is only needed for AED devices that are currently marketed. AED accessories do not need to have an intent to file.

For AED devices that were identified in the intent to file, a PMA must be submitted within 18 months of the date of the final order, which would be August 3, 2016. For devices included in the PMA, distribution can continue while the PMA is under review. I also want to note that multiple public access defibrillators may be submitted in a single PMA. Likewise, multiple professional use devices can also be submitted in a single PMA. And necessary AED accessories can also be included in either device PMA.

If a notice of intent to file a PMA for a currently marketed AED device is not submitted within 90 days of the effective date of the final order, or a PMA is not approved, then the manufacturer must cease distribution of the device or the device will deemed to be adulterated, and subject to seizure and condemnation.

Moving to currently marketed AED accessories. The necessary AED accessory is not included in the device PMA and that accessory is currently marketed, the PMA must be submitted within five years of the date of the final order. As with the currently marketed AED devices, distribution can continue while the PMA is under review.

This table summarizes the timeline for submission for AED devices and accessories that are currently marketed. So for the intent to file, AED devices have 90 days in which to submit an intent to file, then the AED's that are included in that intent to file can continue to be distributed for 18 months. AED's that are not included in the intent to file may only be distributed for the next 90 days, or until May 4. For accessories, the intent to file is not applicable.

The timeline for filing a PMA for AED devices that are currently on the market is within 18 months, and for accessories, it's within 60 months. You may continue to distribute those devices that are included in a PMA until a not-approvable decision or a denial decision letter is issued. And of course, you can continue distribution if an approval order is issued.

Next up, for manufacturers, you need to file an intent to file for an existing devices, followed by a PMA. Important to remember that the intent to file is only for AED devices. For AED accessories that you intend to continue to market, you need to file a PMA within five years. For any new device or accessory that is not cleared through the 510(k) process, you need to file a PMA. We also strongly encourage all manufacturers to use a pre-submission process to obtain specific feedback from the agency. This can be with regards to your upcoming submissions or any questions that you have regarding your current devices.

For device users, we encourage you to continue to use the devices as needed and continue to maintain your devices per the manufacturer's instructions.

Now I can take your questions.

Coordinator: Thank you. At this time, if you would like to ask a question, please press Star 1 on your touchtone phone. Please insure your phone is unmuted and record your name clearly at the prompt. Once again, that is Star 1 on your touchtone phone. It takes a few minutes for the questions to come through, please stand by.

Our first question comes from (John Pardo). Go ahead, your line is open.

(John Pardo): Yes, hello. I was wondering, for the devices that are in distribution now, under what paradigm -- PMA or 510(k) -- should manufacturers adhere to when making modifications, both before the PMA is submitted and during review?

(Linda): Certainly. For modifications to existing devices, during this transition period, before a PMA has been approved, it depends on the nature of the change. If there is a change that's needed due to a part obsolescence or due to a safety issue, the agency will work with you to make sure that that change is implemented appropriately. In terms of new features that are being added to a device, those will need to be included in a PMA prior to market distribution.

(John Pardo): Thank you.

Coordinator: Thank you. And I'm showing no further questions at this time. Just one moment, please, we did have a few more questions come through. The next question comes from (Matt Spencer). Go ahead, your line is open.

(Matt Spencer): I was wanting to know if manual defibrillators with an AED function are covered under this order?

(Linda): Yes, any device that has AED function is covered under this order.

(Matt Spencer): Thank you.

Coordinator: Thank you. The next question comes from (Stuart Scholman). Go ahead, your line is open.

(Stuart Scholman): (Matt) asked the question that I wanted to ask. Thank you.

Coordinator: Thank you. Please stand by for the next question. Comes from (Darryl Hughes). Go ahead, your line is open.

(Darryl Hughes): Yes, that question's already by answered by - or asked and answered. Thanks.

Coordinator: Thank you. One moment. The next question comes from (John Pardo). Go ahead, your line is open.

(John Pardo): Thank you. What additional data requirements -- if any -- will FDA impose to device function, which are not associated with AED functionalities, such as monitoring function?

(Linda): So it is the intention of the agency to look at things in the premarket, such that they support the intended use of the device, in much the same way as we have been. Certainly for the AED functions they need to have a reasonable assurance of safety and effectiveness, but we would not expect any change to the - say monitoring functions or the ECG functions that currently exist on some of the monitor defibrillators. We would not expect that premarket bar to be any different.

(John Pardo): As a follow up question, may I ask one more question?

(Linda): Sure.

(John Pardo): We interpreted - we read the rule and interpreted to include accessories associated with necessary AED functionality and exclude accessories not necessary for the AED functionality. Is that interpretation correct?

(Linda): Yes, the accessories that are not necessary for the AED functionality may very well be covered under a different regulation, but they are certainly not part of this order.

(John Pardo): Okay, thank you.

Coordinator: Thank you. And our next question comes from (Senthiel Meckapen). Go ahead, your line is open.

(Senthiel Meckapen): I think my question has been answered, but I (unintelligible) prior person. I want to give another example like an accessory -- I (unintelligible) call it like a cabinet that controls the temperature of the AED, how would you - which audit it falls under? I'd like an example.

(Linda): So I would imagine that the smart cabinets that control the AED's, certainly it's going to depend on the functionality that is included in that smart cabinet. But cabinets by themselves should not be covered under the final order. However, I would encourage you to send in a question to the agency with specific functionality for any specific cabinet that might have additional capabilities, just to make sure we're all on the same page.

(Senthiel Meckapen): Thank you.

Coordinator: Thank you. And I'm showing no further questions at this time.

Recording: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Coordinator: Seems like we have some more questions.

Coordinator: Just one moment please, for the next question. Coming from (Beverly McGrane). Go ahead, your line is open.

(Beverly McGrane): Yes, hi. This is (Bev McGrane). So I was wondering, the rule talks about the accessories that will not be part of PMA order. If we're adding a new, non-PMA related accessory functionality of the AED, are we going to have to have the 510(k) approved first and then do the PMA?

(Linda): So, I mean, there is a couple questions I think within your question, so let me take a stab at what I believe your question to be. So if you have an accessory that will be covered under a separate regulation, and could be cleared as a 510(k) under a separate regulation, would you need to get it cleared as a 510(k) prior to its incorporation into the AED? And my answer is some of that depends on the business aspect of what you're trying to do. Certainly if you wanted that as a separate accessory, with its own clearance, then you could take it through the 510(k) process. If however, you were only going to use this with a AED, then you would want to get that approved through the PMA for use with the AED.

(Beverly McGrain): Okay, so follow up question to that would be, if that's the case, is that accessory going to be held to the same PMA standards as the AED, or would it be held to the 510(k) standard?

(Linda): So in terms of the necessary data that we would want to see with regards to demonstrating performance, the accessory that would otherwise be 510(k) will be held to the 510(k) performance bar. In as much as the accessory interacts with the AED and may impact the hazards or mitigations associated with that class 3 device, we would want to see that laid out.

(Beverly McGrain): Okay, thank you.

Coordinator: Thank you. Our next question is from (Elaine Duncan). Go ahead, your line is open.

(Elaine Duncan): Yes, you mentioned the pads may be included in the PMA application. So if a pad manufacturer wanted their device - their pad to be included in an AED PMA, the pad manufacturer file this information with the device master file? And, the second part of the question is, does the pad use with the AED require clinical data for use with that pad?

(Linda): So, I'm going to start with the second part of the question, because I think that one's a little more straightforward. The information that we would expect for pads with regards to demonstrating an assurance of safety and effectiveness generally will not require clinical data. And we did discuss that in the final order and in some of the questions in response to the final order - or to the proposed order. Generally speaking, there's andequte animal models and bench testing that can be done with pads to provide the necessary performance data.

As to your first question, if a manufacturer - if a pad manufacturer would like to pursue that way of getting their pads approved in a PMA, then certainly we are open to that discussion, and I would recommend that you coordinate with a AED device manufacturer or - and talk with the FDA about the specifics about how that could be moved forward.

(Elaine Duncan): Thank you.

Coordinator: Thank you. Our next question is going to come from (Larry Star). Go ahead, your line is open.

(Larry Star): Thank you. If for whatever reason, an AED or its accessories do not receive PMA acceptance, is there any requirement to inform the users that this situation exists?

(Linda): So certainly we would want to - the manufacturers to make aware certainly for devices that are currently market approved. We would be interested in making sure that all of the devices that were under that umbrella, that are currently distributed, everyone would know the status of that. As to the exact regulatory actions that we would take with regards to those devices, that would be something that we would have to look into and is a little bit beyond what I am prepared to discuss today. But I understand your question and it's definitely something that we need to make sure that we're aware of going forward.

(Larry Star): Okay, thanks.

Coordinator: Thank you. Our next question is from (Darryl Hughes). Go ahead, your line is open.

(Darryl Hughes): Thank you. To what extent does this order apply to distributers of recertified AED's?

(Linda): As we discussed in the final order in the questions, and our responses to the questions that came as a response to the proposed order, refurbishers and resellers, if they meet the definition of a device manufacturer, would fall under this final order. So if there is a refurbisher that is taking the devices and changing them in some way, or fixing them and reselling them, then they would fall under this final order. And just to point to, I believe that was question 16 in the final order.

(Darryl Hughes): Now, as a follow up, I take that as long as there's not a change to the specs from the original - how the AED was originally manufactured, there would not be a need for compliance with the PMA process by the recertified distributer, correct?

(Linda): I think there is - we need to be clear about what it means to be a refurbisher and I would like to make sure that we're all talking about the same thing. Certainly, if you change the specification, it's very clear. If you're not changing the specification, but you're fixing the device in any way, then I believe we also consider that a refurbisher and you would be subject to this order.

(Darryl Hughes): Okay, thank you.

(Linda): And if you have any questions about whether the actions that you are doing with regards to the device, then I would recommend that you come in and talk to us and we can be more specific about your specific case.

(Darryl Hughes): Okay, thank you.

Coordinator: Thank you. And again, as a reminder, if you do have a question please press Star 1 on your touchtone phone. Once again, that is Star 1if you have a question. Our next question will come from (Kathy Roberts). Go ahead, your line is open.

(Kathy Roberts): I have a question about AED's that are at user sites that are no longer being manufactured by the company. Will they need to be included in the PMA in order for us to continue selling the necessary accessories?

(Linda): They will not need to be included in the PMA for you to continue selling the necessary accessories for those devices. And that is one of the reasons that we allow the accessory manufacturers the extended five year time table for the PMA's, so that the situation that you're describing would be covered.

(Kathy Roberts): Thank you.

Coordinator: Thank you. Our next question is from (John Pardo). Go ahead, your line is open.

(John Pardo): Yes, is the (unintelligible) a noble approach that was outlined recently and draft guidance on accessories, does that apply here?

(Linda): In terms of the accessories that were not identified in the final order, then certainly that draft guidance should be considered when preparing submission.

Coordinator: Thank you. And I'm showing no further questions at this time. One moment please. Next question is from (Greg Rubin). Go ahead, your line is open.

(Greg Rubin): With the new PMA submissions, will that drive a pre-PMA inspection for the manufacturer?

(Linda): Yes.

(Greg Rubin): Thank you.

Coordinator: Thank you. Our next question is from (Senthiel Neckapen). Go ahead, your line is open.

(Senthiel Neckepen): Yes, I have a question based on a scenario. Say if the accessories are - you know might be apply for the accessories and it's been approved, and the same accessories could be used on a new product for example, would we then require another PMA to be submitted with the new product PMA?

(Linda): So I'm going to rephrase your question, just to make sure that I completely understand what you're asking. If you have an accessory that has been cleared through the 510(k) process, and that same accessory without changes is able to be used with a different product, can that 510(k) clearance still be used for the new product? And I'm going to go back to new accessory, and any new accessory would need to have a PMA approval prior to marketing. An existing accessory, which it sounds like what you're talking about, would not need to have a PMA in house for five years.

(Senthiel Neckepen): Okay, thank you.

Coordinator: Thank you. Our next question is from (Elisabeth George). Go ahead, your line is open.

(Elisabeth George): Yes, just to follow up on your comment about the accessories for non-presently selling defibrillators. You mentioned that's why you had the 60 month timeframe, but in some cases that device may continue to be utilized well beyond the five years. So is the expectation that those accessories then be handled as a PMA, or does it go well beyond that 60 month time frame?

(Linda): The final order allows for five years and we certainly will reconsider as we get closer to that timeframe about the number of devices impacted and how we will proceed.

(Elisabeth George): Thank you.

Coordinator: Thank you. And I'm showing no further questions at this time.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation, along with the slide presentation

and transcript will be available on the CDRH webinar page at www.fda.gov\cdrhwebinar by Friday, February 13. If you have additional questions about this final order, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Again, thank you for participating. This concludes today's webinar.

Coordinator: Thank you. That does conclude today's conference. Thank you for participating. You may disconnect at this time.

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