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Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date

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Guidance for Industry, Stakeholders, Health Care Professionals, and Food and Drug Administration Staff

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For questions about this document, contact OHT2: Office of Cardiovascular Devices/DHT2A: Division of Health Technology 2A at (301) 796-6883.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2020-D-1877. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA is issuing this guidance to revise its compliance policy regarding the deadline for filing premarket approval (PMA) applications for previously cleared accessories necessary to the operation of automated external defibrillator (AED)[1] systems. This policy is based, in part, in consideration of the burden on healthcare facilities as they transition to FDA-approved AEDs and on the manufacturers as they prepare to implement the PMA requirements while addressing the challenges related to Coronavirus Disease 2019 (COVID-19).

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

[1] On February 3, 2015, FDA published a final rule calling for the submission of premarket approval applications for AEDs and their necessary accessories (80 FR 5674). AEDs that were cleared prior to the implementation of this regulatory requirement are sometimes referred to as "legacy" AEDs.

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 guidance means that something is suggested or recommended, but not required.

II. Background

In February 2015, FDA published a final order requiring the submission of PMA applications for new and existing AEDs and necessary AED accessories.[2] The final order required the submission of a PMA application for any preamendments[3] and substantially equivalent necessary AED accessory — such as batteries, pad electrodes, adapters, and hardware keys for pediatric use — within 90 days of the date of the final order; however, the final order also stated that FDA did not intend to enforce compliance with the PMA submission requirement for these necessary AED accessories for 60 months following the date of the final order, which was February 3, 2020.

In response to feedback from stakeholders, FDA stated it did not intend to enforce the PMA submission requirement for their products until February 3, 2021. During the COVID-19 pandemic, FDA has received many inquiries from facilities where AEDs are installed about whether FDA would extend the time during which FDA does not intend to enforce compliance with the deadline for submitting PMAs for previously cleared necessary AED accessories so these facilities would have more time to procure FDA-approved AEDs. In addition, for those manufacturers that have not already met the PMA requirements for their necessary AED accessories, preparing to implement these requirements while addressing the challenges related to COVID-19 could pose challenges and divert resources from COVID-19 response efforts. Accordingly, to the extent that this policy helps manufacturers and healthcare facilities remain focused on public health needs related to COVID-19, we conclude that revising our policy with regard to enforcement of PMA requirements for necessary AED accessories for an additional period of time, as described in this guidance, presents a less burdensome policy consistent with the public health.

The policy in this guidance applies to previously cleared accessories necessary for an AED to detect and interpret an electrocardiogram and deliver an electric shock (e.g., battery, pad electrode, adapter, and hardware key for pediatric use), which are regulated as Class III devices under 21 CFR 870.5310, product codes[4] MKJ and NSA.

[2] Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems; Republication, 80 FR 5674 (February 3, 2015).
[3] "Preamendments" refers to devices that were in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments to the FD&C Act.
[4] For more information, see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

III. Policy Regarding Enforcement of Premarket Approval Requirements for Necessary AED Accessories

At this time, in light of the considerations above, FDA does not intend to enforce compliance with the premarket approval requirements under section 515 of the FD&C Act for necessary AED accessories (such as batteries, pad electrodes, adapters, and hardware keys for pediatric use) until February 3, 2022.

This February 3, 2022 date might not align with the end-of-life dates previously communicated by manufacturers to customers of certain AED systems. Therefore, FDA recommends that manufacturers of those AED systems communicate with customers and continue to facilitate customer transition to FDA-approved AEDs as appropriate.