On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Contains Nonbinding Recommendations

Annual Reports for Approved Premarket Approval Applications (PMA)

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 16, 2019.

Document originally issued on February 10, 2014.

For questions regarding the use or interpretation of this guidance document in the review of annual reports for premarket approval applications (PMA), please contact ORP: Office of Regulatory Programs/Division of Regulatory Programs 1: Submission Support at 301-796-5640.

For questions regarding the application of this guidance to devices regulated by the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development (OCOD) at 1-800- 835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.



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

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2006-D-0039. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1585 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.

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Annual Reports for Approved Premarket Approval Applications (PMA)

Guidance for Industry and Food and Drug Administration Staff

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

Devices subject to premarket approval (PMA) under section 515 of the Federal Food, Drug, and Cosmetic Act (the Act) are subject to periodic reporting requirements set forth in the PMA approval order (21 CFR 814.82(a), 21 CFR 814.84(b)). This guidance document describes the information required to be submitted in annual reports under 21 CFR 814.84(b), additional information requirements that may be imposed by approval order under 21 CFR 814.82(a), and FDA's recommendations for the level of detail the applicant should provide in the annual report. It also identifies the steps FDA staff generally take when reviewing annual reports, the resources available to assist staff in their reviews, and the actions they may recommend after reviewing annual reports. This guidance document is intended to help ensure that annual reports are complete and that the actions of CDRH and CBER staff are consistent.

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

A. General Background

FDA needs to be able to rely on a variety of postmarket controls to assure the continuing safety and effectiveness of a medical device after it is distributed. FDA believes that data and information gathered in the postmarket setting are critical to our continued confidence in the safety and effectiveness of the marketed device. Annual reports are one of the important tools that FDA relies on to gather information about the device in its post-approval setting.

Annual reports contain a variety of information, including information about manufacturing changes, design changes, and labeling changes that were made during the preceding year for the PMA product. This guidance recommends that this and other information be analyzed and presented in annual reports in a way that will be most useful to both the applicant and FDA. For example, the guidance recommends that the applicant describe in detail the rationale for changes made to the device, including, for example, whether the changes were the result of device improvement/enhancement, product complaints, or adverse events. This explanation will give FDA a more complete picture of the post-market safety profile of the device. The guidance also recommends that the applicant include a summary of all changes that were made to the device during the reporting period, including listing all supplements submitted during the reporting period and, if approved, their approval date. Having the information submitted in this way will help ensure that limited Agency resources are devoted to assessing meaningful information rather than requiring FDA to sift through vast amounts of data that have not been systematically reviewed by the firm.

Annual reports that contain clear descriptions and meaningful information are an important tool for the Agency and the industry to assure postmarket safety and protect the public. When applicants prepare and provide to FDA in annual reports the type of analysis this guidance describes, industry and FDA are better positioned to recognize and address possible safety issues.

B. Regulatory Background

In PMA approval orders, FDA requires that PMA applicants submit post-approval periodic reports (e.g., annual reports at intervals of 1 year (unless otherwise specified) from the date of approval of the original PMA) to FDA in accordance with 21 CFR 814.82(a)(7) and 814.84(b). Section 814.84(b) describes the information required to be included in periodic reports.

Unless FDA specifies otherwise, a periodic report must:

1. Identify changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b); and

2. Contain a summary and bibliography of the following information not previously submitted as part of the PMA:

i. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

ii. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.

If, after reviewing the summary and bibliography, FDA concludes that the Agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.

The PMA applicant is primarily responsible for determining whether changes to the device design, labeling, or manufacturing processes impact safety or effectiveness and, thus, require a PMA Supplement or 30-Day Notice. This guidance is not intended to define when a PMA applicant should submit a new original PMA or any type of PMA Supplement. For that type of guidance, please refer to the FDA guidance, "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process."[1]

PMA applicants are also subject to other reporting requirements. In accordance with 21 CFR 814.84(a), the applicant must comply with Medical Device Reporting (MDR) requirements, 21 CFR Part 803, and any applicable requirements in other regulations or by order approving the device, including Post-Approval Study Reports if FDA has imposed continuing evaluation (post-approval study) requirements on the device in the PMA approval order, 21 CFR 814.82(a)(2).

FDA believes that the types of information described in this guidance and the types of review, summary, and analyses we are recommending should be readily available to applicants because they currently collect this information and conduct these analyses as part of their compliance with the quality system regulations (21 CFR Part 820). For example, design controls already require the type of look back and assessment that we are suggesting be part of the annual report (21 CFR 820.30).

III. Scope

In the PMA approval orders, we typically specify that PMA applicants submit a report one (1) year from the date of approval of the original PMA and annually thereafter. Therefore, the periodic report is usually referred to as an "annual report." There may be circumstances, however, where FDA specifies more frequent periodic reports that provide all of the same information that is reported annually. This guidance addresses FDA's expectations concerning annual and other periodic reports. This guidance addresses but does not describe in detail Post-Approval Study reports (see Section VI).

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process

IV. Contents of an Annual Report

A complete annual report (in an acceptable eCopy format)[2] should include all of the information described below. The eCopy must be accompanied by a single paper copy of your signed cover letter.

Cover Letter for an Annual Report

FDA recommends that the applicant include a cover letter for the PMA annual report. The cover letter should include:

- PMA Number
- Device Name (including device family name or model names and numbers)
- Company Name
- Date of Report
- Reporting Period (i.e., the dates the reporting period begins and ends)

Identification of the Changes Made During the Reporting Period

For changes that are the subject of an approved or pending PMA Supplement or 30-Day Notice submitted in the reporting year, we recommend that the applicant identify the document number assigned by FDA and status of the document (e.g., approved with approval date, or pending).

Certain changes related to the device documentation or manufacturing process documentation, such as rewording for clarification, translating from one language to another, correcting typographical errors, and moving component characteristics from a notation in an engineering drawing to a different document, such as an Standard Operating Procedure, generally do not need to be reported in the annual report (21 CFR 814.39(b)). In general, such changes do not affect the design, performance, labeling, or processing of the device, and affect only how the characteristics are documented. These types of changes have been commonly referred to as "document to file" by industry and should be kept in your design history file.

For each change that was identified as an annual reportable change that did not require a PMA Supplement or 30-Day Notice under 21 CFR 814.39(b), we recommend you identify the following, as applicable:

- description of the change made, including a comparison to the previously approved version;

- rationale for making the change, including identification of event(s) related to the rationale/reason for the change (e.g., MDR number(s), recall number);

- listing/grouping of associated changes that were made to address the same issue; and

[2] Please refer to the FDA guidance, "eCopy Program for Medical Device Submissions" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions), for additional information on the eCopy program.

- scientific and/or regulatory basis for concluding that the change had no impact on safety or effectiveness in order to allow FDA to understand how the applicant determined the change did not require a PMA Supplement or 30-Day Notice.

FDA recommends that the applicant provide separate tables for manufacturing changes, design changes, and labeling changes, and that the applicant identify changes that are associated with each other so it is clear which changes are linked. For example, certain changes might be linked to each other because they are intended to improve or correct the same aspect of the device. See below for the recommended format for the Changes Tables.

Design [or Manufacturing or Labeling] Changes Table

Change Order Number or unique way to identify change	**Type of Change (design, labeling, manufacturing)**	**Description of Change**	**Rationale for Change (including identification of event(s) linked/leading to reason for change)**	**Related Changes**	**Why Change Does Not Impact S&E***

* Verification and Validation data should not be submitted by an applicant in an annual report (or reviewed by FDA in a report).

Below are examples of rationales for device changes. FDA recommends the applicant specify all of the relevant reasons that apply to the change, including but not limited to those we have listed here, as this list is not exhaustive of all possible reasons for making device changes:

- made as a result of a device improvement or enhancement;
- made as a result of an adverse event, device defect, or failure reported to the applicant or identified in the literature (if the event resulted in an MDR, FDA recommends that the applicant provide the applicable MDR number(s));
- made in response to a customer complaint, request, or suggestion;
- made in association with any recall or corrective action, see also 21 CFR 820.100 (FDA recommends that the applicant list the recall number or identify if considered a class III recall);

- related to an FDA Safety Alert, Public Health Notification, or warning letter;

- related to any public disclosure or communication on the applicant's part (e.g., "Dear Doctor" or "Dear Patient" letters, Technical Bulletins, or other written communication to practitioners, patients, or sales staff). FDA recommends that the applicant include a copy of the communication in the annual report.

Summary and Bibliography of Reports of Scientific Investigations and Literature

The applicant is required to provide a summary and bibliography of reports in the scientific literature concerning the device that are known, or that reasonably should be known to the applicant, and that were not previously submitted as part of the PMA application (21 CFR 814.84(b)(2)(ii)). The summary must also include unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices that are known or that reasonably should be known to the applicant (21 CFR 814.84(b)(2)(i)).

The summary should include a discussion of how the results and conclusions in the reports and literature could impact the known safety and effectiveness profile of the device as well as a description of your plans for assessing the potential impact. If after reviewing the literature, no issues are identified regarding safety and effectiveness, please clearly state this in the annual report.

If, after reviewing your annual report, FDA concludes that we need an actual copy of a published or unpublished report, FDA will notify the applicant, who must submit a copy in response, as required by 21 CFR 814.84(b)(2)(ii). However, if the applicant anticipates that FDA will need a copy of any of these reports, applicants may provide a copy in the annual report on their own initiative.

Information on Devices Shipped or Sold

To help FDA assess the public health impact of the previously requested information, FDA has required in approval orders issued after August 1, 2009 that the applicant provide FDA with data about the number of devices shipped or sold during the reporting period.[3] For device implants, data regarding the number of devices actually implanted should be provided, if it is available.

V. FDA's Review of Annual Reports

FDA's review of annual reports allows the Agency to assess several important issues related to postmarket safety and effectiveness of approved devices. These issues include the nature and adequacy of reported modifications and the adequacy of report documentation. If, after reviewing the annual report, FDA needs additional information, or if we believe the device modifications that the applicant has reported require a PMA Supplement or a 30-Day Notice,

[3] As provided in 21 CFR 814.82(a)(9), FDA may find this information to be necessary to provide a continued reasonable assurance of the safety and effectiveness of the device.

FDA will notify the applicant via letter or email.[4]

FDA reviews most annual reports within 90 days of receipt. In general, our review memoranda follow the format described below.

Reported Changes and Rationale for the Changes

FDA's review memorandum will summarize the changes described in the annual report and our evaluation of those changes. The review memorandum will also describe FDA's understanding of the applicant's rationale for the changes and our assessment of the rationale. The memorandum will clearly indicate whether FDA believes the changes described by the applicant are appropriate for an annual report or should have been described in a PMA Supplement or a 30-Day Notice.

Device Change and Bibliography Information

FDA will evaluate your summary of the changes made to the device. As appropriate, FDA also plans to search the MAUDE database and review certain other FDA records to assess the post-market safety profile of your device.

FDA will evaluate the information on the changes made to the device and the rationale for the changes, as well as the information the applicant submits from published and unpublished reports, and literature to determine if any of this information demonstrates that the safety and effectiveness profile of the device has changed. FDA can then determine whether any action (e.g., a labeling change) is necessary to ensure the continued safety and effectiveness of the device.

VI. FDA's Recommendations

Generally, FDA's review will result in one of the following recommendations:

Acknowledgement of Review of Annual Report

When FDA reviews the annual report and has no further questions, we will issue a letter or send an e-mail to inform the applicant of this status and indicate that no additional information is needed.

Request Additional Information

If the applicant has not provided all the information required for an annual report, or FDA finds that the information provided is not sufficient to allow a complete review, we will request additional information by letter or email. If FDA needs only clarification of an issue, we will work interactively with the applicant via telephone or e-mail, whichever FDA believes will be the most efficient.

Changes Not Appropriate for an Annual Report

If FDA determines that a change made to the device required a PMA Supplement or 30- Day

[4] For additional information about email communications with CBER, please see SOPP 8119: Use of Email for Regulatory Communications, available at https://www.fda.gov/media/108992/download.

Notice under 21 CFR 814.39, and one was not submitted, we will notify the applicant by letter or email.[4] In general, FDA will issue a letter notifying the applicant that a PMA Supplement or 30-Day Notice is required for the change and request that the appropriate submission be provided within a specified timeframe. However, there may also be instances when OC review is necessary to determine if any additional regulatory actions are warranted.

VII. Other Reports - Post-Approval Study Reports

As described in 21 CFR 814.82(a)(2), FDA may require continuing evaluation (post-approval studies) and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use (post-approval study reports). If your approval order identifies post-approval studies you must conduct, the order will describe the purpose of the studies and how frequently you must submit post-approval study reports.

Please submit your annual report and post-approval study report separately, even if they are due at the same time, and identify the date that you submitted your post-approval study report in your annual report. This will facilitate FDA's review because the post-approval study report and the annual report are typically reviewed for different purposes.[5]

[5] See the guidance, "Procedures for Handling Post-Approval Studies Imposed by PMA Order," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-pma-order.