GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF; CENTER FOR DEVICES AND RADIOLOGICAL HEALTH APPEALS PROCESSES

0910- NEW

SUPPORTING STATEMENT

A. Justification

Abstract

This guidance document describes the processes available to outside stakeholders to request additional review of decisions or actions by Center for Devices and Radiological Health (CDRH or the Center) employees. The Food and Drug Administration (FDA) is seeking approval for the new reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in this guidance. Individuals outside of FDA who disagree with a decision or action taken by CDRH employees and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including: requests for supervisory review of an action, petitions, and hearings. Of these, by far the most commonly used is a request for supervisory review under 21 CFR 10.75 (a "10.75 appeal"). Section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 603 of the FDA Safety and Innovation Act of 2012, includes new requirements pertaining to the process and timelines for 10.75 appeals of "significant decisions" regarding 510(k) premarket notifications, applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs). In this guidance document, the term "significant decision" will refer to significant decisions pertaining to these submissions.

1. Circumstances Making the Collection of Information Necessary

This guidance document describes the processes available to outside stakeholders to request additional review of decisions or actions by CDRH employees. FDA is seeking approval for the new reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in this guidance.

Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including: requests for supervisory review of an action; petitions; and hearings. Of these, by far the most commonly used is a request for supervisory review under 21 CFR 10.75 (a "10.75 appeal"). Section 517A of the FD&C Act, added by section 603 of the FDA Safety and Innovation Act of 2012, includes new requirements pertaining to the process and timelines for 10.75 appeals of "significant decisions" regarding 510(k) premarket notifications, applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs).

A request for review under section 10.75 should be based on the information that was already present in the administrative file at the time of the decision that is being reviewed as provided in 21 CFR 10.75(d). New section 517A of the FD&C Act refers to significant decisions regarding The information in the administrative file for premarket notifications (section 510(k)); PMAs (section 515); and IDEs (section 520(g)) submissions is collected under existing regulations which specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of medical devices. The information collections associated with these regulations are currently approved by the Office of Management and Budget as follows: the collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910-0078.

While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the decision under review. The guidance describes the collection of information not expressly specified under existing regulations: the submission of the request for review, minor clarifications as part of the request, and supporting information.

Although submitters may employ whatever format best meets their needs when requesting supervisory review of decisions, the guidance suggests a commonly-used format intended to facilitate the Center's timely processing of requests for review and to ensure that the submitter's request includes sufficient information to permit a substantive review of the issues under appeal. The Center recommends a cover letter which contains: (1) a statement that a review is being requested under 21 CFR 10.75 at a particular supervisory level for the specific submission, (2) a request for either an in-person meeting or a teleconference to provide the submitter an opportunity to make the case directly to the review authority, or a request for expedited review without a meeting or teleconference; (3) if desired, a request for the review authority to convene a meeting of the relevant Advisory Panel, or a request for referral of the review to outside expertise along with a justification for either such request; (4) a clear statement of the issue under appeal dispute and a discussion of why the relief sought by the submitter should be granted; and (5) an explicit statement of the relief or action being requested. The submitter is encouraged to submit a list of references to documents already in the administrative file or may include copies of these documents with the cover letter.

Based on CDRH's experience with appeals, the Agency expects that most persons requesting additional review of decisions will have gathered the materials listed in the previous paragraph when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates the collection of information attributed solely to the guidance will be minimal.

The Medical Devices Dispute Resolution Panel (DRP) is intended to provide a means for independent review of a scientific controversy between a stakeholder and FDA. The DRP fulfills two statutory mandates under the FD&C Act: the requirement of section 515(g)(2)(B) for review of PMA approvals and denials by an advisory committee "which may not be panels under section 513; and the requirement of section 562 for a process for review of scientific controversies by a sponsor, applicant, or manufacturer of a drug or device product for which no other section of the FD&C Act "provides a right of review of the matter in controversy…" CDRH recommends that a request to convene the DRP follow the same guidelines described for requests for supervisory review of decisions.

2. Purpose and Use of the Information Collection

As described under Circumstances Making the Collection of Information Necessary, the guidance document provides information to outside stakeholders about the processes available to request additional review of decisions or actions by CDRH employees. The guidance also provides the new procedures and timelines for appeals of significant decisions under 21 CFR 10.75, as established by section 603 of FDASIA in July 2012.

By providing a suggested format which outlines what types of information should be in an appeals cover letter and encouraging submitters to reference specific documents in the administrative file which are germane to the appeal request, CDRH expects that a predictable and reliable process for appeals will reduce the burden to outside stakeholders requesting an appeal. The materials that submitters provide to CDRH in a request for supervisory review will also facilitate the Center's processing of requests, help ensure that the submitter's request includes sufficient information to permit a substantive review of the issues under appeal, and help meet statutory time frames for reviews of significant decisions.

Respondents are sponsors, applicants, or manufacturers of medical devices.

Required for ICRAS: (2) Private Sector, business

3. Use of Improved Information Technology and Burden Reduction

CDRH permits submitters of requests for appeals to provide either hard copy or electronic documents via the processes established for premarket submissions and applications. In the Federal Register of March 20, 1997, FDA published a final rule establishing electronic records, electronic signatures, and electronic submissions which manufacturers, sponsors, or applicants could choose to utilize, rather than hard copy, for premarket submissions. CDRH has actively encouraged respondents to submit required or recommended information through electronic means or to provide electronic copies of such information.

FDA estimates that 70% of respondents will use electronic means to fulfill the Agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection for this guidance document does not duplicate any other information collection and is not collected by any other agency in the Government. In an appeals request, CDRH does not require the submission of any information already contained in the administrative file, but allows the submitter to simply reference documents in the file. Submitters also have the option of providing electronic or hard copies of documents, if they prefer.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that 1,450 respondents are considered small businesses.

FDA helps to minimize the impact on small businesses through personalized assistance and guidance provided by the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) within CDRH. DSMICA's technical and regulatory staff is available to respond to questions. A toll-free dedicated telephone number, available Monday through Friday from 8 a.m. to 5 p.m., was established to facilitate this direct communication link. The Division also maintains an E-mail account and a website which firms may use to obtain regulatory compliance information.

DSMICA participates in and presents conferences, workshops, and seminars for industry and develops and disseminates publications and educational materials. These efforts help assure that the burden on small manufacturers is minimized.

6. Consequences of Collecting the Information Less Frequently

This information is only collected if an outside stakeholder disagrees with a decision or action taken by CDRH and requests an Agency review of the decision under 21 CFR 10.75.

If this information is not collected, CDRH will not be able to determine whether or not an outside stakeholder's appeal is a request for supervisory review of a significant decision under section 517A of the FD&C Act or whether a scientific controversy under dispute can be accurately assessed.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of December 28, 2011 (76 FR 81511). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   The FDA will not provide any payments or gifts to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    The confidentiality of the information submitted under this guidance is governed by 21 CFR Part 20 and appropriate FDA regulations (807.95 for premarket notification; 814.9 for PMAs; and part 812 for IDEs).

    Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory disclosure of government records (5 U.S.C. 552(b)(1-9). One such provision, 5 U.S.C. 552(b)(4) exempts "trade secret and commercial or financial information that is is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

11. Justification for Sensitive Questions

    The information does not contain questions pertaining to any matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

    FDA expects that the respondents to this information collection will be outside stakeholders consisting of medical device manufacturers, sponsors, or applicants.

    12 a. Annualized Hour Burden Estimate

    FDA estimates it will receive 50 requests annually from outside stakeholders requesting additional review of decisions and actions by CDRH employees. The Agency reached this estimate based on data collected by CDRH over the last three years. FDA estimates it will take outside stakeholders approximately 8 hours to prepare a request based on the Agency's experience with past requests.

Table 1 – Estimated Annual Reporting Burden in Hours

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH Appeals Processes Guidance Document	50	1	50	8	400
Total	50	1	50	8	400

12b. Annualized Cost Burden Estimate

FDA estimates an average wage rate of $90.00 per hour for a Senior Regulatory Affairs Manager and $24.35 per hour for an Executive Administrative Assistant for preparing and submitting the information requested under the guidance. These wage estimates are based on figures found in the 2012 Scope of Practice and Compensation Report for the Regulatory Profession, Regulatory Affairs Professional Society (http://www.raps.org/Portals/0/Documents/2012-SoP_Report.pdf) and the May 2011 National Industry-Specific Occupational and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics (http://bls.gov/oes/current/naics4_339100.htm).

Table 2 – Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Senior Regulatory Affairs Manager	350	$90.00	$31,500.00
Executive Administrative Assistant	50	$24.35	$ 1,217.50
Total			$32,717.50

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that 0.5 FTE, at the Grade level 15, Step 5 will be needed to appropriately determine whether an appeal request for review of a decision meets the criteria of a "significant decision" under section 517A of FDASIA. This will be done at FDA headquarters in Silver Spring, MD. The Office of Personnel Management determined that for 2012, the wage rate of for a GS-15-5 in the Washington, DC-Baltimore-Northern Virginia area is $67.21 per hour. $67.21 x 1043 hours (0.5 FTE) results in an annualized cost to the Federal Government of $70,100. (http://www.opm/gov/oca/12tables/indexGS.asp)

15. Explanation for Program Changes or Adjustments

    This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    The results of this information collection are not to be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA will display the OMB approval number and its expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.

B. Statistical Methods (used for collection of information employing statistical methods)

There are no statistical methods being employed in this collection of information.