



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10 and 800

[Docket No. FDA-2016-N-2378]

RIN 0910-AH37

Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement regulations regarding internal agency supervisory review of certain decisions related to devices regulated by the Center for Devices and Radiological Health (CDRH) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to conform to the applicable provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act). FDA is taking this action to codify the procedures and timeframes for supervisory review of significant decisions pertaining to devices within CDRH. FDA is also proposing regulations to provide new procedural requirements for requesting internal agency supervisory review within CDRH of other types of decisions made by CDRH not addressed in FDASIA and the Cures Act. This action is also part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden

reduction, while allowing the Agency to achieve its public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. See section V of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other

information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions.”)

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include Docket No. FDA-2016-N-2378 for “Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health.” Received comments, those filed in a timely manner (see ADDRESSES) will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that

states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5574, Silver Spring, MD 20993-0002, 240-402-0768; or the Ombudsman for the Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave.,

Bldg. 32, Rm. 4282, Silver Springs, MD 20993-0002, 301-796-5669, or
CDRHombudsman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this proposed rule is to implement regulations on the procedures regarding internal agency supervisory review of certain decisions made by CDRH under the FD&C Act. Section 603 of FDASIA added new section 517A to the FD&C Act (21 U.S.C. 360g-1), which was amended by sections 3051 and 3058 of the Cures Act. These provisions established procedures and timeframes for supervisory review under § 10.75 (21 CFR 10.75) of significant decisions by CDRH pertaining to devices. After the enactment of FDASIA, FDA issued a guidance document entitled “Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A--Guidance for Industry and Food and Drug Administration Staff” (Q&A Guidance) to provide interpretation of key provisions of section 517A, including those that pertain to requests for supervisory review of significant decisions by CDRH (Ref. 1). FDA is proposing this regulation to codify (1) the procedures and timeframes for § 10.75 appeals of “significant decisions” by CDRH established under section 517A and (2) the interpretation of key provisions of section 517A of the FD&C Act regarding supervisory review. In addition, the proposed regulations would introduce new procedural requirements for supervisory review within CDRH of other CDRH decisions that were not addressed in FDASIA and the Cures Act.

The proposed regulations will provide transparency and clarity for internal and external stakeholders on CDRH’s process for supervisory review of decisions and will give requesters

new predictability through binding deadlines for FDA action on a request for supervisory review within CDRH and the Center's internal agency review of "significant decisions." Furthermore, this proposal, when finalized, will codify the types of decisions that are considered "significant decisions," for which the timeframes apply. The proposed regulations will also codify the timeframe for submission of requests for the review of other decisions within CDRH.

B. Summary of the Major Provisions of the Proposed Rule

FDA proposes to amend part 10 (21 CFR part 10) by adding § 10.75(e). Section 10.75 currently provides that an interested person outside the Agency may request internal agency review of a decision of an FDA employee. FDA proposes to amend § 10.75 to add paragraph (e), which would require that requests for internal agency supervisory review within CDRH of a decision also comply with proposed § 800.75 (21 CFR 800.75). This proposed change to the regulations would encompass both significant decisions under section 517A of the FD&C Act and other decisions by CDRH employees.

The proposed rule would also add new § 800.75 to part 800 (21 CFR part 800). Proposed § 800.75 would incorporate in the regulations the provisions of section 517A of the FD&C Act for review of "significant decisions" related to devices regulated under the FD&C Act by CDRH. Proposed § 800.75 would define "significant decisions." Section 800.75 would also include the timeframes for submission of requests for internal agency review of significant decisions within CDRH and for responses to such requests.

Proposed § 800.75 would further address requests for supervisory review within CDRH of decisions other than section 517A decisions and would indicate the timeframe for submission of these requests for internal agency review.

C. Legal Authority

FDA's legal authority to implement requirements pertaining to the process and timelines for § 10.75 appeals of decisions within CDRH derives from sections 510(k), 515, 515C, 517A, and 520(g) of the FD&C Act (21 U.S.C. 360(k), 360e, 360e-3, 360g-1, and 360j) and other provisions under which a decision might be appealed, and 701(a) of the FD&C Act (21 U.S.C. 371(a)). Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

We expect the costs and benefits of the proposed rule to be negligible.

II. Background

A. Regulations on Internal Agency Review

FDA has long provided a path for outside parties to request internal agency review of decisions. A procedure for this type of review was first published as a proposed regulation in 1975 (40 FR 40682, September 3, 1975) (Ref. 2). In the preamble for the proposed rule, the Agency recognized that a process for administrative review of Agency decisions would advise outside parties how they should pursue matters that interest and concern them (40 FR 40682 at 40693). A final rule published in 1977 incorporated these provisions into the Code of Federal Regulations at 21 CFR 2.17 (42 FR 4680, January 25, 1977) (Ref. 3).

These regulations provided that any decision of an FDA employee, other than the Commissioner, on any matter was subject to review by the employee's supervisor under any of the following circumstances: (1) at the request of the employee, (2) on the initiative of the supervisor, (3) at the request of any interested person outside of the Agency, or (4) as required by duly promulgated delegations of authority. The review shall be accomplished by consultation between the employee and the supervisor, by review of the administrative file, or both. The

review shall ordinarily follow established Agency channels of supervision. Internal agency review shall be based on the data and information available in the administrative file. If an interested person presents new data or information not contained in the administrative file, then the matter shall be returned to the appropriate lower level within the Agency for a reevaluation based upon the new information (§ 2.17 (1977)).

The following year, in 1978, a proposed rule was published to reorganize and revise the Agency's administrative practices and procedures regulations (43 FR 51966, November 7, 1978) (Ref. 4). When the final rule for this action was published, the regulations for internal agency review were moved from § 2.17 and redesignated as § 10.75 (44 FR 22318, April 13, 1979) (Ref. 5), where these regulations remain today.

In 1998, § 10.75 was amended to add provisions allowing a sponsor, applicant, or manufacturer of a drug or device to request review of a scientific controversy by an appropriate scientific advisory panel or advisory committee (63 FR 63978, November 18, 1998). Aside from the specific situation addressed by the amendment, the elements of internal agency review under § 10.75 relating to who may request the review and the information on which the review must be based remained unchanged.

Section 10.75 contains regulations that establish an orderly process for internal agency review of decisions, based on information in the FDA administrative file. Section 10.75 applies to requests for review of decisions made by any FDA employee, other than decisions by the Commissioner of Food and Drugs. Section 10.75 does not establish timelines for requests for Agency review or for the Agency to act upon these requests. The FDA guidance document entitled "Center for Devices and Radiological Health Appeals Processes--Guidance for Industry

and Food and Drug Administration Staff” describes the § 10.75 appeal processes available to outside stakeholders to request review of decisions or actions by CDRH employees (Ref. 6).

B. Agency Documentation and Review of Significant Decisions Regarding Devices under Section 517A of the Federal Food, Drug, and Cosmetic Act

On July 9, 2012, the FD&C Act (21 U.S.C. 301 *et seq.*) was amended by FDASIA. Section 603 of FDASIA added new section 517A to the FD&C Act, which specifies procedures and timeframes for the supervisory review of significant decisions pertaining to devices regulated by CDRH.

On December 13, 2016, the FD&C Act (21.U.S.C. 301 *et. seq.*) was further amended by the Cures Act. Section 3051 of the Cures Act, “Breakthrough Devices,” added section 515C to the FD&C Act and amended section 517A(a)(1) to include any significant decision by CDRH regarding a request for designation as a breakthrough device under section 515C.

In addition, section 3058, “Least Burdensome Device Review,” of the Cures Act amended section 517A(a) by adding subsection (3), which requires that the substantive summary include a brief statement of how the least burdensome requirements were considered and applied consistent with sections 513(i)(1)(D), 513(a)(3)(D), and 515(c)(5) of the FD&C Act, as applicable.

Section 517A of the FD&C Act provides that any person may request a supervisory review of any significant decision of CDRH regarding the submission or review of a report under section 510(k), an application under section 515, a request for designation under section 515C, or an application for an exemption under section 520(g) of the FD&C Act. Any person may request such review, which may be conducted at the next supervisory level or higher above the individual who made the significant decision. Where the request for supervisory review was

made at the organizational level, any person may request a supervisory review to the next organizational level or higher above the level at which the decision was made. In addition, the Office or Center Director may designate a Deputy Director to be their representative as the authority for a request made to that level. In this situation, a request for review heard by a Deputy is rendered on behalf of the Director and constitutes a review by that level of the organization. (Ref. 6).

Section 517A of the FD&C Act includes specific timeframes both for the person requesting review and for FDA to respond to such a request. A request for review of a significant decision is required to be submitted to FDA not later than 30 days after such decision. In responding to this request, if the requester seeks an in-person meeting or a teleconference review, FDA is required to schedule the requested interaction not later than 30 days after the request is made. FDA is required to issue a decision not later than 30 days after the interaction, or, in the case of a person who does not seek an in-person meeting or teleconference review, FDA is required to issue a decision no later than 45 days after the request for supervisory review is received by FDA. An exception to the timeframes related to scheduling an in-person meeting or teleconference review, and to FDA's decision on a request for supervisory review of the significant decision, is provided in cases that are referred to experts outside of FDA. Although the procedures and timeframes in section 517A of the FD&C Act apply to an initial request for supervisory review of a significant decision by CDRH, CDRH has chosen to enhance transparency and predictability and apply those procedures and timeframes as well to sequential requests for supervisory review of significant decisions that are submitted to CDRH.

III. Legal Authority

We are proposing to codify the procedures and timeframes in section 517A of the FD&C Act, added by section 603 of FDASIA and amended by the Cures Act, for § 10.75 appeals of “significant decisions” regarding the submission or review of a report under section 510(k), an application under section 515, a request for designation under section 515C, or an application for an exemption under section 520(g) of the FD&C Act.

We are also proposing additional procedural requirements for § 10.75 appeals submitted to CDRH of other types of CDRH decisions not addressed in the FDASIA and the Cures Act.

FDA’s legal authority to implement requirements pertaining to the process and timelines for § 10.75 appeals submitted to CDRH derives from sections 510(k), 515, 515C, 517A, and 520(g) of the FD&C Act and other provisions under which a decision might be appealed, and 701(a) of the FD&C Act. Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule

The proposed rule would, if finalized, incorporate the procedures and timeframes in section 517A to an initial or sequential request for supervisory review within CDRH of “significant decisions” by CDRH into FDA’s regulations. The proposed regulations would also introduce new procedural requirements for requests for supervisory review within CDRH under § 10.75 of decisions that do not fall under “significant decisions” under section 517A of the FD&C Act.

FDA proposes to amend part 10 by adding § 10.75(e). Section 10.75 currently provides that an interested person outside the Agency may request internal agency review of a decision of an FDA employee. FDA proposes to amend § 10.75 to add paragraph (e), which would require that requests for internal agency supervisory review within CDRH also comply with proposed

§ 800.75. This proposed change to the regulations would encompass both significant decisions under section 517A of the FD&C Act and other types of decisions.

The proposed rule would add new § 800.75 to part 800. Proposed § 800.75 would incorporate, into the regulations, the provisions of section 517A of the FD&C Act for review of significant decisions related to devices regulated under the FD&C Act by CDRH. Proposed § 800.75 would define “significant decisions.” Section 800.75 would also include the timeframes for submission of requests for internal agency review of significant decisions within CDRH and for responses to such requests.

Proposed § 800.75 would further address the review of decisions other than 517A decisions and would indicate the timeframe for submission of these requests for internal agency review within CDRH.

A. Proposed Revisions to § 10.75

Part 10 would be amended to add § 10.75(e). FDA proposes to add language to clarify that requests by interested persons outside the Agency for internal agency review of a decision within CDRH must also comply with proposed § 800.75. Proposed § 10.75(e) would not be limited to significant decisions under section 517A of the FD&C Act. Rather, proposed § 10.75(e) would also encompass review of decisions other than 517A decisions made by CDRH.

B. Proposed § 800.75

Section 517A of the FD&C Act establishes procedural requirements, including timeframes for a request for internal agency review of a “significant decision” by CDRH. “Significant decision” is not defined in the statutory provision. FDA is proposing to define

“significant decision,” to provide greater clarity regarding which decisions fall within this statutory term.

A “517A decision” would be defined as a significant decision regarding a device as set forth in section 517A of the FD&C Act. We are proposing to use the term “517A decision” rather than the term “significant decision” because we do not want to imply that all other decisions of the Agency that do not fall within section 517A of the FD&C Act are not significant. Similarly, we did not want to use the term “non-significant decision” when speaking of decisions outside of the scope of section 517A, as that might imply some unintended assessment on our part concerning the importance of these types of decisions. In addition, because we are proposing these regulations to include regulatory decisions by CDRH besides those set forth in section 517A, we wanted to avoid any confusion that might occur in distinguishing between these two categories of decisions. For these reasons, we instead are proposing to use the term “517A decision” for those decisions that are identified under section 517A as significant decisions, and to refer to other decisions by CDRH as “non-517A decisions.”

The review procedures under section 517A of the FD&C Act apply only to a request for review of a significant decision by CDRH regarding submission or review of a report under section 510(k) (Premarket Notification), an application under section 515 (Premarket Approval or “PMA”/Humanitarian Device Exemption or “HDE”), a request for designation under section 515C (Breakthrough Devices), or an application for an exemption under section 520(g) of the FD&C Act (Investigational Device Exemption or “IDE”). CDRH is proposing that only the following decisions be considered significant decisions under section 517A of the FD&C Act and, thus, defined for purposes of this proposed rule as “517A decisions”:

- 510(k): Not substantially equivalent; Substantially equivalent.

- PMA/HDE: Not approvable; Approvable; Approval; Denial.
- Breakthrough Devices: Expedited access pathway (Ref. 7) program request for breakthrough designation for devices subject to premarket notification, premarket approval, or de novo requests. Grant; Denial of request for breakthrough designation.
- IDE: Disapproval; Approval.
- Failure to reach agreement on protocol under section 520(g)(7) of the FD&C Act.
- “Clinical Hold” determinations under section 520(g)(8) of the FD&C Act.

In proposing § 800.75, we are mindful that outside parties may use § 10.75 to request review of decisions other than 517A decisions. For this reason, we are also proposing new procedural requirements for internal agency supervisory review within CDRH under § 10.75 of non-517A decisions made by CDRH employees. A request for supervisory review of a CDRH decision other than a 517A decision is to be received no later than 60 days after the date of the decision that is subject to review. Any request received after 60 days in these cases will be denied as untimely, unless CDRH, for good cause related to circumstances beyond the control of the submitter, such as snow emergency, Federal Government shutdown, or other unforeseen emergency event, permits the request to be filed after 60 days.

Section 800.75 proposes that requests for CDRH review of 517A decisions and non-517A decisions must be addressed to the next organizational level or higher above the individual who made the decision. Requests to elevate the review of such decisions should include a rationale. The decision to collapse two or more levels of review or to elevate a review would solely be at CDRH’s discretion. In addition, requesters should have exhausted review through the supervisory chain below the Center Director level prior to request for review at the Center Director level.

As provided in the FDA guidance, entitled “eCopy Program for Medical Device Submissions--Guidance for Industry and Food and Drug Administration Staff” (eCopy guidance), appeals to submission types identified under section 745A(b) of the FD&C Act are subject to the electronic format requirements. (Ref. 8). Therefore, 10.75 requests for supervisory review of 517A decisions within CDRH, and certain decisions other than 517A decisions, must be submitted in accordance with section 745A(b) and the standards established by the eCopy guidance, when applicable. In addition, requests for breakthrough designation under section 515C of the FD&C Act for devices under sections 510(k), 513(f)(2), and 515(c) of the FD&C Act would be considered “presubmissions” to those submission types as identified under section 745A, and, therefore, requests for breakthrough designation would be subject to section 745A(b), and likewise, § 10.75 requests for review within CDRH.

Further, § 800.75 proposes that requests for supervisory review of CDRH decisions other than 517A decisions must be sent to the CDRH Ombudsman, and those decisions, other than 517A decisions not subject to section 745A, are to be submitted in electronic format. Further instructions will be provided regarding submission of such requests in electronic format.

V. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 90 days after the date of publication of a final rule in the *Federal Register* or at a later date if stated in the final rule.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under EO 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). EO 12866 and 13563 direct us to assess all costs and benefits of

available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). EO 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is not a significant regulatory action as defined by EO 12866. It has been determined that this proposed rule is an action that does not impose more than de minimis costs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we anticipate that the costs of the rule would be de minimis, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule.

The proposed rule would (1) define “517A decision,” (2) apply to requests submitted to CDRH for review of 517A decisions and decisions other than 517A decisions made by CDRH,

and (3) establish timelines and procedures for an interested person to request supervisory review of these decisions by CDRH. By setting specific timelines for persons to submit requests for supervisory review, the proposed rule would help clarify the supervisory review process and provide firms with an incentive to promptly submit review requests. The proposed rule would also establish timelines for CDRH review of 517A decisions, reducing uncertainty about when interested persons would know the outcome of their requests for supervisory review. Because the proposed rule would not change the effort needed to prepare and submit a request for supervisory review, we anticipate that affected interested persons would incur only negligible costs to read and learn about the provisions of the proposed rule. We do not expect additional costs for FDA.

We received 42 requests for review in 2013, 28 requests for review in 2014, 20 requests for review in 2015, and 20 requests for review in 2016. We estimate that each request for review required 70 hours of CDRH staff time. One possible benefit of the proposed rule, if finalized, is that it may reduce the number of hours required per request for review. If firms have more clarity about the request for review process, they may not have to spend as much time navigating the process, and we may not need to spend as much time guiding them through the process.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information regarding the appeals process for devices in the guidance document entitled “Center for Devices and Radiological Health Appeals Processes” have been approved under OMB control number 0910-0738; 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 for De Novo classification requests have been approved under the OMB control number 0910-0844; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910-0078; 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 814, subpart H (humanitarian use devices) have been approved under OMB control number 0910-0332.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m.,

Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. “Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A--Guidance for Industry and Food and Drug Administration Staff,” July 30, 2014, available at:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf>.

2. 40 FR 40682, September 3, 1975

[http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/040171&collection=fedreg§ion=0&id=179&print=1§ioncount=1&ext=.pdf&nocover=.](http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/040171&collection=fedreg§ion=0&id=179&print=1§ioncount=1&ext=.pdf&nocover=)

3. 42 FR 4680, January 25, 1977

[http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/042016&collection=fedreg§ion=0&id=250&print=1§ioncount=1&ext=.pdf&nocover=.](http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/042016&collection=fedreg§ion=0&id=250&print=1§ioncount=1&ext=.pdf&nocover=)

4. 43 FR 51966, November 7, 1978

[http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F043216&id=186§ion=&skipstep=1&fromid=186&toid=238&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range.](http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F043216&id=186§ion=&skipstep=1&fromid=186&toid=238&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range)

5. 44 FR 22318, April 13, 1979

[http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F044073&id=258§ion=&skipstep=1&fromid=258&toid=376&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range.](http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F044073&id=258§ion=&skipstep=1&fromid=258&toid=376&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range)

6. “Center for Devices and Radiological Health Appeals Processes--Guidance for Industry and Food and Drug Administration Staff,” May 17, 2013, available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf>.

7. “Expedited Access for Premarket Approval and *De Novo* Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions--Guidance for Industry and Food and Drug Administration Staff,” April 13, 2015, available at: <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393978.pdf>.

8. “eCopy Program for Medical Device Submissions--Guidance for Industry and Food and Drug Administration Staff,” December 3, 2015, available at: <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf>.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 800

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 10 and 800 be amended as follows:

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. In § 10.75, add paragraph (e) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(e) Each request by an interested person for review of a decision within the Center for Devices and Radiological Health shall also comply with § 800.75 of this chapter.

PART 800--GENERAL

3. The authority citation for part 800 is revised to read as follows:

Authority: 5 U.S.C. 551-559; 21 U.S.C. 301-399f.

4. In part 800, add § 800.75 to subpart C to read as follows:

§ 800.75 Requests for supervisory review of certain decisions made by the Center for

Devices and Radiological Health.

(a) The following definitions shall apply to this section:

(1) *FDA* means the Food and Drug Administration.

(2) *517A decision* means a significant decision made by the Center for Devices and Radiological Health, as set forth in section 517A of the Federal Food, Drug, and Cosmetic Act, and includes one of the following decisions:

(i) A substantially equivalent order under § 807.100(a)(1) of this chapter, or a not substantially equivalent order under § 807.100(a)(2) of this chapter;

(ii) An approval order under § 814.44(d) of this chapter, an approvable letter under § 814.44(e) of this chapter, a not approvable letter under § 814.44(f) of this chapter, or an order denying approval under § 814.45 of this chapter;

(iii) An approval order under § 814.116(b) of this chapter, an approvable letter under § 814.116(c) of this chapter, a not approvable letter under § 814.116(d) of this chapter, or an order denying approval under § 814.118 of this chapter;

(iv) A grant or denial of a request for breakthrough device designation under section 515C of the Federal Food, Drug, and Cosmetic Act;

(v) An approval order under § 812.30(a) of this chapter or a disapproval order under § 812.30(c) of this chapter;

(vi) A failure to reach agreement letter under section 520(g)(7) of the Federal Food, Drug, and Cosmetic Act; or

(vii) A clinical hold determination under section 520(g)(8) of the Federal Food, Drug, and Cosmetic Act.

(3) *CDRH* means the Center for Devices and Radiological Health.

(b) Submission of request.

(1) Review of 517A decisions.

(i) An initial or sequential request for supervisory review within CDRH of a 517A decision under § 10.75 of this chapter must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act; marked “Appeal: Request

for Supervisory Review;” and received by CDRH no later than 30 days after the date of the decision involved. Any such request for supervisory review not received by CDRH within 30 days after the date of the decision involved is not eligible for review. Except as provided in paragraph (b)(1)(ii) or (iii) of this section, FDA will render a decision within 45 days of the request for supervisory review.

(ii) A person requesting supervisory review under paragraph (b)(1)(i) may request an in-person meeting or teleconference with the supervisor reviewing the request for supervisory review. Except as provided in paragraph (b)(1)(iii) of this section, if a request for in-person meeting or teleconference is included in the request for supervisory review to CDRH, CDRH will schedule the meeting or teleconference to occur within 30 days of receipt of the request. Except as provided in paragraph (b)(1)(iii) of this section, a decision will be rendered within 30 days of such meeting or teleconference.

(iii) The timeframes for CDRH to render a decision provided in (b)(1)(i) and (ii), and the timeframe to schedule an in-person meeting or teleconference review in (b)(1)(ii) of this section do not apply, if a matter related to the 517A decision under review is referred by CDRH to external experts, such as an advisory committee, as provided in § 10.75(b) of this chapter.

(2) An initial or sequential request for supervisory review within CDRH under § 10.75 of this chapter of a decision other than a 517A decision that is not received by CDRH within 60 days after the date of the decision involved will be denied as untimely, unless CDRH, for good cause, permits the request to be filed after 60 days. An initial or sequential request for supervisory review within CDRH of a decision other than a 517A decision must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic

Act, when applicable; marked, "Appeal: Request for Supervisory Review" in the subject line of the electronic request; and sent to the CDRH Ombudsman at CDRHombudsman@fda.hhs.gov.

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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