



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: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing a final rule to amend its regulations regarding internal agency supervisory review of certain decisions related to devices regulated by the Center for Devices and Radiological Health (CDRH or the Center) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to conform to the applicable provisions in the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act). This final rule codifies the procedures and timeframes for supervisory review of significant decisions pertaining to devices within CDRH. FDA is also finalizing 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: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule 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: *With regard to the final rule:* 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 Spring, MD 20993-0002, 301-796-5669, or CDRHombudsman@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule 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 (Pub. L. 112-144) 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 (Pub. L. 114-255). These provisions established procedures and timeframes for supervisory review under Title 21 of the Code of Federal Regulations (CFR) § 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 of the FD&C Act, including those that pertain to requests for supervisory review of significant decisions by CDRH (available at:

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf>). FDA is finalizing 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 regulations codify new procedural requirements for supervisory review within CDRH of other CDRH decisions that were not addressed in FDASIA and the Cures Act.

The final rule provides transparency and clarity for internal and external stakeholders on CDRH's process for supervisory review of decisions and provides 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 final rule codifies the types of decisions that are considered "significant decisions," for which the timeframes apply. The final regulations also codify the timeframe for submission of requests for the review of other decisions within CDRH.

B. Summary of the Major Provisions of the Final Rule

FDA is amending 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 is amending § 10.75 to add paragraph (e) to require that requests for internal agency supervisory review of a decision within CDRH also comply with

new § 800.75 (21 CFR 800.75). This change to the regulations encompasses both significant decisions under section 517A of the FD&C Act and other decisions by CDRH employees for which review is requested through the supervisory chain within CDRH.

The final rule also adds new § 800.75 to part 800 (21 CFR part 800). Section 800.75 incorporates 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. Section 800.75 defines “significant decisions.” Section 800.75 also includes the timeframes for submission of requests for internal agency review of significant decisions within CDRH and for responses to such requests.

Section 800.75 further addresses requests for supervisory review within CDRH of decisions other than section 517A decisions and indicates 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, 515B, 517A, and 520(g) of the FD&C Act (21 U.S.C. 360(k), 360e, 360e-3, 360g-1, and 360j(g)) 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 final rule will be negligible.

II. Table of Abbreviations/Commonly Used Acronyms in this Document

| Abbreviation | What it Means |
|-------------------|--|
| 510(k) | Premarket notification |
| 513(f)(2) | De Novo classification process |
| 517A decision | A significant decision regarding a device as set forth in section 517A of the FD&C Act |
| Agency | Food and Drug Administration |
| CDRH or Center | Center for Devices and Radiological Health |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments, 42 U.S.C. 263a |
| EO | Executive Order |
| FD&C Act | Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 <i>et seq.</i> |
| FDA | Food and Drug Administration |
| FDASIA | Food and Drug Administration Safety and Innovation Act |
| FDASIA amendments | Section 603 of FDASIA |
| HDE | Humanitarian Device Exemption |
| IDE | Investigational Device Exemption |
| Non-517A decision | CDRH decisions outside the scope of section 517A of the FD&C Act |
| NSE | Not substantially equivalent |
| OMB | Office of Management and Budget |
| Part 10 | 21 CFR part 10 |
| PMA | Premarket approval |
| PRA | Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520 |
| PHS Act | Public Health Service Act |
| Section 10.75 | 21 CFR 10.75 |
| U.S.C. | United States Code |
| We or us | Food and Drug Administration |

III. Background

A. Need for the Regulation/History of the Rulemaking

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). In the preamble for that proposed rule, the Agency recognized that a process for administrative review of Agency decisions would advise outside parties on 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 § 2.17 (21 CFR 2.17) (42 FR 4680, January 25, 1977).

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 (42 FR 4680 at 4707).

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). When the final rule for that 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), 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 (available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf>).

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 was further amended by the Cures Act. Section 3051 of the Cures Act, “Breakthrough Devices,” added section 515B to the FD&C Act (as amended by section 901(f)(2) of the FDA Reauthorization Act of 2017 (Pub. L. 115-52)) and amended section 517A(a)(1) to include any significant decision by CDRH regarding a request for designation as a breakthrough device under section 515B.

In addition, section 3058, “Least Burdensome Device Review,” of the Cures Act amended section 517A(a) by adding paragraph (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 (21 U.S.C. 360c(i)(1)(D), 360c(a)(3)(D), and 360e(c)(5)), 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 515B, 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 subordinate to be their representative, as the authority for a request made to that level. In this situation, a request for review heard by a designated subordinate is rendered on behalf of the Director and constitutes a review by that level of the organization.

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.

On January 17, 2018, FDA published a proposed rule to incorporate the procedures and timeframes in section 517A of the FD&C Act to an initial or sequential request for supervisory review within CDRH of "significant decisions" by CDRH into FDA's regulations (83 FR 2388). The proposed regulation also introduced 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. We are finalizing this rule as described below.

1. Amendments to § 10.75

Part 10 is amended to add § 10.75(e). FDA is adding language to clarify that requests by interested persons outside the Agency for internal agency review of a decision within CDRH must also comply with new § 800.75. The amendments to § 10.75(e) are not limited to significant decisions under section 517A of the FD&C Act. Rather, § 10.75(e) also encompasses supervisory review within CDRH of decisions other than 517A decisions made by CDRH.

2. New § 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 defines "significant

decision” in § 800.75 to provide greater clarity regarding which decisions fall within this statutory term.

A “517A decision” is defined as a significant decision made by CDRH, as set forth in section 517A of the FD&C Act. We use the term “517A decision” rather than the term “significant decision” because we do not want to imply that any other decisions of CDRH that do not fall within section 517A of the FD&C Act are not significant. Similarly, we do not 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 include regulatory decisions by CDRH in addition to those set forth in section 517A of the FD&C Act, we believe that this will avoid any confusion that might occur in distinguishing between these two categories of decisions. For these reasons, we instead are using the term “517A decision” for those decisions that are identified under section 517A as significant decisions and 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 Application (PMA)/Humanitarian Device Exemption (HDE)), a request for designation under section 515B (Breakthrough Devices), or an application for an exemption under section 520(g) of the FD&C Act (Investigational Device Exemption (IDE)). Under the new § 800.75, only the following decisions are considered significant decisions under section 517A of the FD&C Act and, thus, defined for purposes of this rule as “517A decisions”:

- 510(k): Not substantially equivalent; Substantially equivalent.
- PMA/HDE: Not approvable; Approvable; Approval; Denial.
- Breakthrough Device Designation Request (request for breakthrough designation for devices subject to premarket notification, premarket approval, or De Novo classification process (see “Breakthrough Devices Program: Guidance for Industry and FDA Staff”; available at: <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm581664.pdf>): 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.

We are mindful that outside parties may use § 10.75 to request review of decisions other than 517A decisions. For this reason, we provided 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 provides 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 (available at: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf>). 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) of the FD&C Act and the standards established by the eCopy guidance, when applicable. In addition, requests for breakthrough designation under section 515B 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) of the FD&C Act, and likewise, § 10.75 requests for review within CDRH.

Further, § 800.75 requires that requests for supervisory review of CDRH decisions other than 517A decisions be sent to the CDRH Ombudsman, and if subject to section 745A of the FD&C Act, are to be submitted in electronic format.

B. Summary of Comments in Response to the Proposed Rule

The comments on the proposed rule were generally favorable and supportive of the proposal to codify the procedures and timeframes for supervisory review of 517A and non-517A decisions pertaining to devices regulated by CDRH.

A comment appreciated the Agency's actions to clarify the CDRH process for supervisory review of decisions along with deadlines for certain FDA actions. Another comment, however, requested clarification about escalating review beyond the next organizational level above the decision maker (telescoping review). Another comment questioned whether the scope of significant decisions under section 517A of the FD&C Act should be expanded; specifically, recognition of additional CDRH decisions as 517A decisions. A comment was received on clarifying timeframes for receipt of a substantive summary upon request as required for a 517A decision. The comment also expressed concern over the proposed timeframe for requests for supervisory review of non-517A decisions, requested clarification on specific timeframes for non-517A decisions for requesters that seek to schedule a meeting or teleconference, and requested the addition of timeframes for when CDRH will render a decision.

IV. Legal Authority

We are issuing this final rule 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 515B, or an application for an exemption under section 520(g) of the FD&C Act.

We are also finalizing additional procedural requirements for § 10.75 appeals submitted to CDRH of other types of CDRH decisions not addressed in 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, 515B, 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.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received various comments from a trade organization and an individual on the proposed rule by the close of the comment period; however, only one commenter provided comments on issues relevant to the proposed rule.

We describe and respond to the comments below. We have separated different issues discussed in the same set of comments and designated them as distinct comments for purposes of our responses. The number assigned to each comment topic is purely for organizational purposes and does not signify the comment's value or importance.

B. Description of Comments and FDA Responses

(Comment 1) One comment appreciates FDA's efforts to provide clarity to industry on the CDRH process for supervisory review of decisions, along with binding deadlines for certain FDA actions related to supervisory review and other related timeframes.

(Response 1) FDA proposed the regulation to provide clarity on the process for supervisory review and instruction on how external stakeholders, who disagree with a decision or action taken by CDRH, may seek resolution. FDA believes a well-informed process for CDRH reviews of significant decisions under 517A of the FD&C Act, as well as non-517A decisions,

promotes consistency, predictability, efficiency, and a transparent pathway of our review process.

(Comment 2) A comment requested that FDA expand the definition of significant decision as set forth in section 517A of the FD&C Act by including: (1) a grant or denial of Clinical Laboratory Improvement Amendments (CLIA) waiver and a (2) grant or decline of a De Novo classification request.

(Response 2a) When Congress passed CLIA in 1988 (Pub. L. 100-578), amending section 353 of the Public Health Service (PHS) Act (42 U.S.C. 263a), they established clinical laboratory quality standards for all laboratory testing. While the Centers for Medicare & Medicaid Services has primary responsibility for administering CLIA, FDA also has certain responsibilities under CLIA, including categorizing tests as high complexity, moderate complexity, or waived. However, Congress did not include CLIA waived categorization under the PHS Act as regulatory decisions that trigger the requirements under section 517A of the FD&C Act. Therefore, FDA does not intend to expand the definition of a significant decision to the grant or denial of a CLIA waiver because it is outside the scope of the types of decisions expressly included under section 517A of the FD&C Act.

(Response 2b) FDA recognizes that the De Novo classification process is an important part of our regulatory framework. In accordance with section 513(f)(2)(A)(i) of the FD&C Act, any person who submits a 510(k) for a type of device that has not been previously classified under the FD&C Act, and that is classified into class III, may request, after receiving written notice of such classification, FDA to classify the device based on the criteria set forth in section 513(a)(1) of the FD&C Act. Under section 513(f)(2)(A)(ii) of the FD&C Act, a person who determines that there is no legally marketed device upon which to base a determination of

substantial equivalence may request FDA to classify the device based on the criteria set forth in section 513(a)(1) of the FD&C Act without first submitting a 510(k). The process created by section 513(f)(2) of the FD&C Act, which was added by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) and referred to therein as the Evaluation of Automatic Class III Designation, is what is now referred to as the De Novo classification process. Although the decision to grant or decline a De Novo request is within FDA's regulatory authority, it is not a decision type identified in section 517A of the FD&C Act as a significant decision. Because section 517A of the FD&C Act does not identify decisions on requests under section 513 of the FD&C Act as one of the types of significant decisions subject to section 517A, FDA believes that a De Novo request appropriately remains within the regulatory category of a non-517A decision.

(Comment 3) One comment requested that FDA permit the collapsing of two or more levels of review, which is otherwise referred to as "telescoped review" to support assessment at the appropriate level and, alternatively, recommended emphasizing that requesters should exhaust review through the supervisory chain below the Center Director level prior to request for review at the Center Director level, absent adequate rationale.

(Response 3) FDA has recognized that CDRH preserves "telescoped review" as a discretionary action in matters pertaining to regulatory issues, new policy questions, or highly complex scientific questions. As explained in the guidance entitled "Center for Devices and Radiological Health Appeals Processes: Guidance for Industry and Food and Drug Administration Staff," engagement of a next-level supervisor in a matter under dispute does not necessarily disqualify the next-level supervisor from hearing the dispute on appeal; however, elevation of a dispute may be appropriate if the next-level supervisor has been significantly and

substantively involved in the regulatory action under review. Certain circumstances may also warrant referral of the review directly to the next-level supervisor, up to and including the Center Director. In these situations, the Center intends that the review will be undertaken and decided by the next-level supervisor. For example, circumstances such as imminent risk to public health may warrant elevation of a Division-level appeal directly to the Center Director. A stakeholder wishing to elevate a dispute should indicate a request for telescoped review with an accompanying rationale. The decision to collapse two or more levels of review or to elevate a review is made solely at the Center's discretion and the Center intends to document the rationale for the decision in the review decision letter.

Absent approval for "telescoped review," requesters must exhaust review through the supervisory chain below the Center Director level prior to requesting review at the Center Director level.

(Comment 4) A comment requested clarification on the timeframe for receipt of a substantive summary and requested that FDA allow additional time to request supervisory review following a company's receipt of a substantive summary under section 517A of the FD&C Act.

(Response 4) In accordance with section 517A(a) of the FD&C Act, FDA shall furnish, upon request, a substantive summary of the scientific and regulatory rationale for any significant decision regarding a report under section 510(k), an application under section 515, a request under section 515B, or an application under section 520(g) of the FD&C Act, to the person who is seeking to submit, or who has submitted, such report or application. The substantive summary must include documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion for any such significant decision of

CDRH, as well as a brief statement of how least burdensome requirements were considered and applied consistently with sections 513(i)(1)(D), 513(a)(3)(D), and 515(c)(5) of the FD&C Act, as applicable.

CDRH prepares and furnishes the final decision, as well as the substantive summary of the scientific and regulatory rationale, solely on the basis of the information in the administrative record, including in a report under section 510(k), an application under 515, a request for designation under 515B, or an application for an exemption under 520(g) of the FD&C Act. Therefore, both the substantive summary and the final decision rely upon the same information in the administrative record, including the information submitted by the sponsor or applicant.

Additionally, CDRH provides the information necessary to file an appeal in its final decision rendered for one of these reports or applications, including CDRH's rationale for the decision. In other words, the sponsor or applicant has the requisite information needed to submit an appeal in accordance with the timelines designated in the statute or identified as part of this final rule. While the substantive summary may include additional information, such as documentation of significant controversies or differences of opinion and the resolution of such, if applicable, that additional information is not necessary to file an appeal. Nonetheless, CDRH is committed to its current practice of furnishing the request for a substantive summary in a timely manner.

(Comment 5) Another comment suggested that FDA update the final rule to include the following: (1) revise the deadline for requests for supervisory review of non-517A decisions from 60 to 90 days and, in the alternative and (2) further clarify the meaning of "good cause" as well as expand "good cause" to include matters pertaining to public health and other justifications.

(Response 5a) Although section 517A of the FD&C Act does not require FDA to implement procedures regarding CDRH decisions other than for 517A decisions, we are mindful that outside parties may use § 10.75 to request review of non-517A decisions. For this reason, we proposed that 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. Any request received after 60 days in these cases will be denied as untimely absent good cause.

We believe 60 days is timely and appropriate for submission of a request for supervisory review of a non-517A decision. We note that this timeframe is twice as long as that for submission of a request for supervisory review of a 517A decision. The primary purpose regarding the deadline of a request for supervisory review of non-517A decisions in this final rule is to provide predictability, and to ensure that such requests are filed in a timely manner. We believe that the timely filing of such requests within the 60-day timeframe will aid CDRH in efficiently handling disputes of non-517A decisions. However, expanding the 60-day timeframe for a request for supervisory review of a non-517A decision may negatively impact other decisions on CDRH regulated medical products. For example, a longer deadline may delay actions and resolutions of other pending matters that may be interrelated. This could negatively affect FDA's ability to act timely in fulfilling its mission to protect and promote the public health. For these reasons, we believe 60 days is an appropriate and reasonable timeframe.

(Response 5b) On the occasion of an unforeseen emergency event, FDA will consider the basis for causes beyond the control of the submitter. As such, FDA may permit the request for supervisory review of a non-517A decision to be filed after 60 days for good cause related to a snow emergency, Federal Government shutdown, or other unforeseen emergency event. We believe that good cause related to "other unforeseen emergency event" can include issues

impacting public health. If a request for supervisory review of a non-517A decision is filed after 60 days, FDA will consider whether there is good cause for extending the timeline based on the circumstances.

(Comment 6) A comment requested that FDA provide specific timelines for non-517A decisions related to when CDRH will schedule a meeting or teleconference, if requested by the person requesting supervisory review and when CDRH will render a decision if no teleconference or meeting is requested.

(Response 6) We disagree that timelines for these actions are needed for FDA to provide timely responses for supervisory review of non-517A decisions. This final rule does not negatively affect CDRH's current practice of providing timely responses regarding requests for supervisory review of non-517A decisions. Apart from this rulemaking, we continue to work with industry and welcome stakeholder feedback on how to improve our communication regarding how CDRH will respond to an appeal of an adverse non-517A decision.

VI. Effective Date

This rule will become effective 30 days after its publication in the *Federal Register*.

VII. Economic Analysis of Impacts

We have examined the impacts of the final 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). EOs 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 final rule is not a significant regulatory action as defined by EO 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we lack information about the number of firms affected and because the affected firms will incur minimal costs to read and understand the rule, we certify that the final 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 \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

In our preliminary regulatory impact analysis, we estimated that the costs and benefits of the rule would be negligible. We received no comments on our preliminary regulatory impact analysis of the proposed rule and thus retain our original estimate for the final regulatory impact analysis. Because the final rule does not change the effort needed to prepare and submit a request for supervisory review, we anticipate that affected firms will incur only negligible costs to read and learn about the provisions of the final rule. The final rule will clarify the supervisory review process. However, we do not expect additional costs for FDA.

VIII. 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.

IX. Paperwork Reduction Act of 1995

This final rule contains previously approved information collections found in FDA regulations and guidance. 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 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, subparts A through E (premarket approval) have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H (humanitarian use devices) have been approved under OMB control number 0910-0332; the collections of information regarding “Requests for Feedback on Medical Device Submissions” have been approved under OMB control number 0910-0756; the collections of information in the guidance document, “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information regarding “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices: Guidance or

Industry and Food and Drug Administration Staff” have been approved under OMB control number 0910-0598; and the collections of information regarding “Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff” have been approved under OMB control number 0910-0607.

X. Federalism

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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 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.

XI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

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, 21 CFR parts 10 and 800 are 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. 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) *Definitions.* 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 515B 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) of this section, 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) *Supervisory review.* 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: June 20, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: June 25, 2019.

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.