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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 16

[Docket No. 02N-0251]

Presiding Officers at Regulatory Hearings

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations governing who may act as a presiding officer at a regulatory hearing. This action amends the regulations to permit an administrative law judge (ALJ) to act as a presiding officer and provide the appropriate delegations of authority. FDA is taking this action to increase the pool of qualified personnel available as presiding officers, thereby increasing the efficiency with which the agency conducts regulatory hearings, beginning with responding to hearing requests and continuing through issuance of written hearing reports. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: This rule is effective December 30, 2002. Submit written or electronic comments on or before October 29, 2002. If FDA receives no significant adverse comments within the specified comment period, the agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of the Chief

Counsel (GCF-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7144.

SUPPLEMENTARY INFORMATION:

I. Discussion

FDA's procedures for a regulatory hearing are set forth in part 16 (21 CFR part 16) of the agency's regulations. "Part 16 hearings" are offered under numerous statutory and regulatory provisions. Section 16.1 provides a list of statutes and regulations in which part 16 hearings are available.

Currently § 16.42(a) provides that an FDA employee to whom the Commissioner of Food and Drugs (the Commissioner) delegates the authority, or any other FDA employee to whom such authority is redelegated, can serve as the presiding officer at a regulatory hearing. In turn, § 5.30(c) (21 CFR 5.30(c)) delegates authority to preside at and conduct a regulatory hearing to the Chief Mediator and Ombudsman for the Agency; the Directors and Deputy Directors of the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation Research; Regional Directors; District Directors; the Director of the St. Louis Branch; and such other FDA official as the Commissioner may designate by memorandum in the proceeding.

FDA believes that the addition of the ALJ to the list of those delegated to conduct regulatory hearings would increase the pool of qualified personnel available to preside at regulatory hearings. In addition, by virtue of the nature of an ALJ's training and experience adjudicating disputes, FDA believes that an ALJ would be appropriately suited to conduct regulatory hearings. Therefore, the agency is amending §§ 5.30(c) and 16.42(a) to permit an ALJ to preside at and conduct regulatory hearings before the agency.

The regulations pertaining to ALJs issued by the Office of Personnel Management (OPM) (5 CFR 930.209(b)), provide that an agency may assign an ALJ, by detail or otherwise, to perform duties that are not the duties of an ALJ without prior approval by OPM when the duties are not inconsistent with the duties and responsibilities of an ALJ, the assignment is not to last longer than 120 days; and the ALJ has not had an aggregate of more than 120 days of such assignments or details in the preceding year. However, OPM's regulations under 5 CFR 930.209(c) also state that on a showing that it is in the public interest,

OPM may authorize a waiver from the 120-day limitation.

For the reasons already discussed, FDA believes it would be in the public interest to permit an ALJ to preside at and conduct part 16 hearings.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule revises §§ 5.30(c) and 16.42(a) to permit an ALJ to preside at and conduct regulatory hearings before the agency. The action taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment by October 29, 2002, the agency will publish a document in the **Federal Register** before November 28, 2002, confirming the effective date of the final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment also states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before November 28, 2002.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Legal Authority

The broad rulemaking authority conferred on FDA by the U.S. Congress under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 201 *et seq.*) permits the agency to amend its regulations as contemplated by this direct final rule. Section 701(a) of the act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for efficient enforcement of the act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies 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). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive order and in the other two statutes. This rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this rule would have on small entities. Because the rule will amend only internal agency procedures, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531) requires that agencies prepare a

written statement of anticipated costs and benefits before issuing any proposed or final 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 million or more (adjusted annually for inflation) in any one year * * *.” This final rule imposes no Federal mandate that will result in such an expenditure. Therefore, FDA is not required to prepare a cost/benefit statement.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This direct final rule does not require information collection. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 16 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATIONS

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2 605; 7 U.S.C. 138a, 2217; 15 U.S.C. 638, 1261–1282, 1451–1461, 3701–3711a; 21 U.S.C. 61–63, 141–149, 301–394, 467f, 679(b), 801–886, 1031–1309, 1401–1403; 35 U.S.C. 156; 42 U.S.C. 238, 241, 242, 242a, 242l, 242n, 242o, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300ar–25–28, 300cc, 300ff, 1395y, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. In § 5.28 revise paragraph (c)(1), redesignate paragraph (c)(10) as paragraph (c)(11), and add new paragraph (c)(10) to read as follows:

§ 5.28 Hearings.

* * * * *

(c) * * *

(1) The Director, Office of the Ombudsman, Office of External Relations, Office of the Commissioner.

* * * * *

(10) An Administrative Law Judge.

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PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

4. Amend § 16.42 by revising paragraph (a) to read as follows:

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

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Dated: August 7, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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