

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 91N-0257]

Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is promulgating a new regulation to describe how the agency will determine which component within FDA will have primary jurisdiction for the premarket review and regulation of: (1) A combination drug, device, or biologic product or (2) any drug, device, or biologic product where the center with primary jurisdiction is unclear or in dispute. This rule describes how to identify the agency's assigned review component which will, in most cases, eliminate the need for a sponsor to obtain approval from more than one FDA component for a combination product.

DATES: These regulations are effective November 21, 1991. Submit written comments by December 23, 1991.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Edwin V. Dutra, Jr., Office of the Commissioner (HF-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

SUPPLEMENTARY INFORMATION:

I. Background

For many years, the agency has been confronted with questions as to which center within FDA should regulate a particular product. For example, in the early 1970's, the agency had to determine where radiopharmaceuticals, radiobiologicals, and in vitro diagnostic products would be regulated. Over time, other products such as medicated wound dressings, bone cement containing an antibiotic, and dental composites with fluoride have raised similar jurisdictional concerns both inside and outside of FDA. The development of new technologies and biotechnological products presents continuing administrative and jurisdictional challenges to the agency.

As the types of products submitted for review have expanded and

jurisdictional issues multiplied, FDA has dealt with these questions in a variety of ways. In some cases, review responsibility for the regulation of certain very similar products has been divided or shared between centers. Although these and other solutions developed by the agency answered some jurisdictional questions, others were left unanswered.

II. The Safe Medical Devices Act of 1990

The Safe Medical Devices Act (SMDA) of 1990 (Pub. L. 101-629) has the general purpose of improving the regulation of medical devices. Section 16 of the SMDA, however, addresses product jurisdiction questions involving "combination products," i.e., products containing a combination of drugs, devices, and biological products.

Specifically, this section of the new law requires that the agency designate a component of FDA to have primary jurisdiction for the premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product. The designation is to be made based upon a determination of the "primary mode of action" of the combination product. The new provision explicitly states, however, that FDA can use any agency resources necessary to ensure adequate safety, effectiveness, or (in the case of medical devices) substantial equivalence reviews for the products involved. Section 16 of the SMDA also modifies the definitions of "drug" and "device," and requires the agency to publish regulations implementing this section within a year, or by November 29, 1991.

As part of the process of developing these regulations, the FDA ombudsman chaired a public hearing on September 6, 1991 (announced in the *Federal Register* of July 12, 1991 (56 FR 31951)). The hearing panel was comprised of Deputy Directors from the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research. The purpose of the hearing was to give interested persons the opportunity to provide comments and suggestions about the content and scope of this regulation. More than 15 people made oral presentations and over 250 persons attended the hearing. The agency also solicited written comments and suggestions, which were accepted from July 12, 1991 through September 13, 1991 (Docket No. 91N-0257). All comments from the hearing or received in writing have been considered.

III. Highlights of the Final Regulation

This final regulation describes how the agency will determine which component within FDA will have the primary jurisdiction for the premarket review and regulation of a combination product comprised of drugs, devices, or biologics. This regulation, however, is not limited in its scope to the combination products specified in the law. To enhance the efficiency of agency operations, it also applies to any drug, device, or biological product where the jurisdiction is unclear or in dispute. This regulation, however, does not apply to foods, veterinary products, or cosmetics. The agency is aware that such products may present jurisdictional issues, and will further consider whether they should subsequently be included in this rule.

The regulation specifies how a sponsor can obtain an agency determination early in the process, before any required filing, which agency component will have primary jurisdiction for the premarket review and regulation of the product. The regulation also establishes a "product jurisdiction officer" within FDA's Office of the Commissioner to oversee these procedures and processes. The FDA Ombudsman is the Product Jurisdiction Officer.

A. Scope

This regulation applies to two categories: First, any product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug and Cosmetic Act (the act) as amended by section 16 of the Safe Medical Devices Act of 1990 (21 U.S.C. 353(g)(1)); and, secondly, any drug, device or biological product where the agency component with primary jurisdiction for the premarket review and regulation is unclear or in dispute.

As set forth in § 3.2(e) of this final rule, the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic (for example, a syringe prefilled with a drug); or two or more separate products packaged together as one unit (for example, a lumbar puncture kit containing drapes, needles, tubes, a syringe, a local anesthetic and a topical antiseptic). A combination product is also a product that is intended for use only with an approved product where both are required to achieve the intended use, indication, or effect, and the labeling of the approved product needs to be changed to reflect this use (for example,

a device to aerosolize medication that works only with a specific drug that when given as an aerosol must be used with this device and that, as a consequence, is labeled for this route of administration using only this device). Finally, a combination product is any investigational product that is intended to be used only with another investigational product where both are required to achieve the intended use, indication, or effect, for example, a novel catecholamine administered by a computerized pump that is to be developed as a pharmacological cardiac stress test.

Thus, the definition of a combination product is intended to exclude most concomitant use of drugs, devices, and biological products. The definition also excludes products comprised exclusively of two or more drugs, two or more devices, or two or more biologicals.

B. Contents of the Regulation

Section 3.4(a) of this rule implements the statutory mandate that the designation of the agency component with primary jurisdiction shall be based on the primary mode of action of the product at issue. Section 3.4(b) of this rule provides that the designation of an agency component does not preclude consultations with other agency components and, where appropriate, does not preclude requiring the approval of a second application, ordinarily by the lead center. In addition, where the agency finds it is necessary, the agency reserves the option to require separate applications to be approved by separate agency components. FDA recognizes that requiring the approval of a second agency component would represent the exception rather than the rule and, in those instances, the reviews will be coordinated to the greatest extent possible.

Section 3.5 of this rule describes how to identify the designated agency component and discusses the intercenter agreements which allocate among the centers primary responsibility for certain products or categories of products. Section 3.6 of this rule identifies a product jurisdiction officer with whom sponsors may file a request for designation of the agency component with primary jurisdiction. Section 3.7 of this rule specifies to whom and when to make a request, and the information to be set forth in the request for designation, including the sponsor's recommendation as to which center should have primary jurisdiction.

Under § 3.8 of this rule, the procedures and time periods applicable to FDA actions on requests for

designation are set forth, including the procedures to be used if a sponsor disagrees with a designation. Section 3.9 of this rule specifies that once a designation has been made, it can be modified with the written consent of the sponsor or, where necessary, without the sponsor's consent to protect the public health or for other compelling reasons. Section 3.10 of this rule provides that the statutory and regulatory time periods for review of premarket submissions and marketing approval applications is stayed by a filing with or review by the product jurisdiction officer.

This regulation has prospective applicability only. Thus, any marketing application (biologics product license application, premarket approval application, or new drug application), pending on or before the effective date of this regulation is not subject to this regulation. A sponsor of a pending marketing application who wants to use the new procedures will have to withdraw its application and resubmit it. The agency may elect to shift responsibility for investigational products consistent with this rule and the other documents discussed below in section III.D. of this preamble.

C. Authority for This Regulation

This rule provides an administrative mechanism to determine which agency component has responsibility for the review of an application. The agency determined that this is "a matter relating to agency management" and a rule of "agency organization, procedure, or practice" and, as such, it is exempt from notice and comment under the Administrative Procedure Act (5 U.S.C. 553 (a)(2) and (b)(A)). The Commissioner also finds good cause under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e) to forgo notice and comment as it would be unnecessary and contrary to the public interest to delay implementation of this rule. As provided in FDA's administrative practices and procedures regulation (21 CFR 10.40(e)), FDA is providing an opportunity for public comment on whether the regulation should be modified or revoked.

D. Other Documents

In this issue of the *Federal Register* the agency is also publishing a notice of availability of guidance documents that are entitled "intercenter agreements." These three guidance documents specify the designated agency component for certain products and categories of products. In addition, this issue contains regulations that, for the three centers involved with this rule, amend 21 CFR part 5 to vest in each center the

approval authority of the other two centers, and to delegate authority under section 503(g) of the act concerning combination products from the Commissioner to the product jurisdiction officer.

IV. Paperwork Reduction Analysis

This rule does not add any information collection requirements to the premarket submissions which are already required for applications affecting drugs, devices, and biologic products. Although the rule requires the submission of this information earlier in the process, the information submitted under this rule by an applicant will be added to the applicant's premarket submission and will not need to be resubmitted at a later time.

V. Environmental Impact Statement

The agency has determined under 21 CFR 25.24(a)(8), 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.

VI. Economic Assessment

In accordance with Executive Order 12291, FDA analyzed the potential economic effects of this rule. The agency has determined that the rule is not a major rule as defined by the Order. The agency has not received any information or comments that would alter its determination.

VII. Comments

Interested persons may, on or before December 23, 1991, submit written comments regarding this rule to the Dockets Management Branch (address above). 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 3

Medical devices, Drugs, Biologics, Antibiotics, Authority delegations, Administrative practice and procedure.

Therefore, under the Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 3 is added as follows:

PART 3—PRODUCT JURISDICTION

Subpart A—Assignment of Agency Component for Review of Premarket Applications

Sec.

- 3.1 Purpose.
- 3.2 Definitions.
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- 3.10 Stay of review time.

Subpart B—[Reserved]

Authority: Secs. 201, 501, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 530-542, 701(a), 706, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 360gg-360ss, 371(a), 376, 381, 394); secs. 215, 351 of the Public Health Service Act (42 U.S.C. 216, 282).

Subpart A—Assignment of Agency Component for Review of Premarket Applications

§ 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Pub. L. 101-629), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological. This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device.

§ 3.2 Definitions.

For the purpose of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency component* means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Drug Evaluation and Research.

(c) *Applicant* means any person who submits or plans to submit an application to the Food and Drug Administration for premarket review. For purposes of this section, the terms "sponsor" and "applicant" have the same meaning.

(d) *Biological product* has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) *Combination product* includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

(f) *Device* has the meaning given the term in section 201(h) of the act.

(g) *Drug* has the meaning given the term in section 201(g)(1) of the act.

(h) *FDA* means Food and Drug Administration.

(i) *Letter of designation* means the written notice issued by the product jurisdiction officer specifying the agency component with primary jurisdiction for a combination product.

(j) *Letter of request* means an applicant's written submission to the product jurisdiction officer seeking the

designation of the agency component with primary jurisdiction.

(k) *Premarket review* includes the examination of data and information in an application for premarket review described in sections 505, 507, 510(k), 513(f), 515, or 520(g) or 520(l) of the act or section 351 of the Public Health Service Act of data and information contained in any investigational new drug (IND) application, investigational device exemption (IDE), new drug application (NDA), antibiotic application, biological product or establishment license application, device premarket notification, device reclassification petition, and premarket approval application (PMA).

(l) *Product* means any article that contains any drug as defined in section 201(g)(1) of the act; any device as defined in section 201(h) of the act; or any biologic as defined in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(m) *Product jurisdiction officer* is the person or persons responsible for designating the component of FDA with primary jurisdiction for the premarket review and regulation of a combination product or any product requiring a jurisdictional designation under this part.

(n) *Sponsor* means "applicant" (see § 3.2(c)).

§ 3.3 Scope.

This section applies to: (a) Any combination product, or

(b) Any product where the agency component with primary jurisdiction is unclear or in dispute.

§ 3.4 Designated agency component.

(a) To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product. Where the primary mode of action is that of:

(1) A drug (other than a biological product), the agency component charged with premarket review of drugs shall have primary jurisdiction;

(2) A device, the agency component charged with premarket review of devices shall have primary jurisdiction;

(3) A biological product, the agency component charged with premarket review of biological products shall have primary jurisdiction.

(b) The designation of one agency component as having primary jurisdiction for the premarket review and regulation of a combination product does not preclude consultations by that component with other agency

components or, in appropriate cases, the requirement by FDA of separate applications.

§ 3.5 Procedures for identifying the designated agency component.

(a)(1) The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research have entered into agreements clarifying product jurisdictional issues. These guidance documents are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and are entitled "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health;" "Intercenter Agreement Between the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research;" "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research." The availability of any amendments to these intercenter agreements will be announced by Federal Register notice.

(2) These guidance documents describe the allocation of responsibility for categories of products or specific products. These intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public.

(3) The sponsor of a premarket application or required investigational filing for a combination or other product covered by these guidance documents may contact the designated agency component identified in the intercenter agreement before submitting an application of premarket review or to confirm coverage and to discuss the application process.

(b) For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application for premarket review should follow the procedures set forth in § 3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

§ 3.6 Product jurisdiction officer.

FDA Ombudsman (HF-7), Food and Drug Administration, rm. 14-84, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306, is the designated product jurisdiction officer.

§ 3.7 Request for designation.

(a) Who should file: the sponsor of:

(1) Any combination product the sponsor believes is not covered by an intercenter agreement; or

(2) Any product where the agency component with primary jurisdiction is unclear or in dispute.

(b) When to file: a sponsor should file a request for designation before filing any application for premarket review, whether an application for marketing approval or a required investigational notice. Sponsors are encouraged to file a request for designation as soon as there is sufficient information for the agency to make a determination.

(c) What to file: an original and two copies of the request for designation must be filed. The request for designation must not exceed 15 pages, including attachments, and must set forth:

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

(2) A description of the product, including:

(i) Classification, name of the product and all component products, if applicable;

(ii) Common, generic, or usual name of the product and all component products;

(iii) Proprietary name of the product;

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product.

(v) Chemical, physical, or biological composition;

(vi) Status and brief reports of the results of developmental work, including animal testing;

(vii) Description of the manufacturing processes, including the sources of all components;

(viii) Proposed use or indications;

(ix) Description of all known modes of action, the sponsor's identification of the primary mode of action, and the basis for that determination;

(x) Schedule and duration of use;

(xi) Dose and route of administration of drug or biologic;

(xii) Description of related products, including the regulatory status of those related products; and

(xiii) Any other relevant information.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction, with accompanying statement of reasons.

(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked "Request for Designation."

§ 3.8 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the centers, specifying the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the center with primary jurisdiction, in accordance with § 3.7(c)(3), shall become the designated agency component.

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to

exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Deputy Commissioner for Operations or the Deputy Commissioner for Policy.

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B—[Reserved]

Dated: November 14, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-27869 Filed 11-20-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to redelegate the Commissioner's authority to designate primary jurisdiction over the premarket review and regulation of combination products under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(1)) a provision of the Safe Medical Devices Act of 1990 to the ombudsman as the product jurisdiction officer, Office of the Commissioner. Under a regulation published elsewhere in this issue of the Federal Register, the FDA ombudsman is the designated product jurisdiction officer.

EFFECTIVE DATE: November 21, 1991.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management

Systems and Policy (HFA-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: In conjunction with section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(1)), a provision of section 16 of the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and implementing regulations to be found at 21 CFR part 3 (created in a companion document also publishing in this issue of the Federal Register), FDA is amending the delegations of authority under 21 CFR part 5 to add new § 5.32. This section gives the FDA ombudsman as the product jurisdiction officer authority to determine whether the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), or the Center for Drug Evaluation and Research (CDER) has primary responsibility for premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the act) or that is a drug, device, or biologic product where the center with primary jurisdiction is unclear or in dispute.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

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

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

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

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

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354-360F, 361, 362, 1701-1706, 2101-2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1-300ff); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. New § 5.32 is added to Subpart B to read as follows:

§ 5.32 Authority relating to determination of product primary jurisdiction.

The FDA ombudsman as product jurisdiction officer is authorized to determine whether the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), or the Center for Drug Evaluation and Research (CDER) has primary responsibility for premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act or that is a drug, device or biologic product where the center with primary jurisdiction is unclear or in dispute.

Dated: November 14, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-27870 Filed 11-20-91; 8:45 am]

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21 CFR Part 5

Delegations of Authority and Organization; Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, and Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to premarket approval of products that are or contain a biologic, a device, or a drug. The amendment grants directors, deputy directors, and certain other supervisory personnel in the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Drug Evaluation and Research (CDER) reciprocal premarket approval authority to approve such products.

EFFECTIVE DATE: November 21, 1991.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: This delegation of authority will assist FDA in implementing section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act