

appears at <http://www.regulations.gov>, you may also file an electronic comment through that Web site. The Commission will consider all comments that [www.ftc.gov](http://www.ftc.gov) forwards to it. You may also visit the FTC Web site at <http://www.ftc.gov/opa/2004/08/franchiserule.htm> to read the Staff Report and the news release describing it, and the FTC Web site at <http://www.ftc.gov/opa/1999/10/franchise-review3.htm> to read the Notice of Proposed Rulemaking and the news release describing this proposed Rule.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

**FOR FURTHER INFORMATION CONTACT:** Steven Toporoff, (202) 326-3135, Division of Marketing Practices, Room H-238, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** The Franchise Rule requires the pre-sale disclosure of material information to prospective franchisees about the franchisor, the franchised business, and the terms and conditions that govern the franchise relationship. The Commission has engaged in an ongoing effort to amend the Franchise Rule, starting with a review of the Franchise Rule in 1995,<sup>1</sup> followed by the publication of an Advanced Notice of Proposed Rulemaking in 1997,<sup>2</sup> and the publication of a Notice of Proposed Rulemaking in 1999.<sup>3</sup>

Pursuant to the Commission's Rules of Practice, and the rulemaking procedures specified earlier in the Notice of Proposed Rulemaking, the Commission now announces the availability of the Staff Report on the Franchise Rule. The Staff Report summarizes the rulemaking record to date, analyzes the various alternatives,

and sets forth the staff's recommendations to the Commission on the revised Rule. The Staff Report has not been reviewed or adopted by the Commission. The Staff Report is available from the Commission's Public Reference Room, Room H-130, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. It is also available on the FTC's Web site, at <http://www.ftc.gov>, by searching on the phrase (with quotation marks): "Staff Report + Franchise".

The Commission invites interested parties to submit written data, views, and arguments on the recommendations announced in the Staff Report, by following the instructions in the **ADDRESSES** section of this Notice. Comments, however, are to be limited to those matters that are already part of the rulemaking record. Further, comments previously submitted in the ongoing rulemaking procedure are already part of the rulemaking record and need not be repeated. Written communications and summaries or transcripts of any oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will also be placed on the public record. See 16 CFR 1.26(b)(5).

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Upon the completion of the comment period, the staff will make final recommendations to the Commission about the Rule. Assuming the Commission adopts the proposed revised Rule, it will publish another **Federal Register** notice in the future with the final text of the revised Rule, a Statement of Basis and Purpose on the Rule, and an announcement of when the revised Rule will become effective.

#### List of Subjects in 16 CFR Part 436

Advertising, Business and industry, Franchising, Trade practices.

**Authority:** 15 U.S.C. 41-58.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 04-19969 Filed 9-1-04; 8:45 am]

**BILLING CODE 6750-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 20

[Docket No. 2004N-0214]

#### Public Information Regulations; Companion Document to Direct Final Rule

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its public information regulations to implement more comprehensively the exemptions contained in the Freedom of Information Act (FOIA). This action incorporates exemptions one, two, and three of FOIA into FDA's public information regulations. Exemption one applies to information that is classified in the interest of national defense or foreign policy. Exemption two applies to records that are related solely to an agency's internal personnel rules and practices. Exemption three incorporates the various nondisclosure provisions that are contained in other Federal statutes. This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**.

**DATES:** Submit written or electronic comments by November 16, 2004.

**ADDRESSES:** You may submit comments, identified by [Docket No. 2004N-0214], by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include [Docket No. 2004N-0214] in the subject line of your e-mail message.

FAX: 301-827-6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the agency name and

<sup>1</sup> 60 FR 17656 (Apr. 7, 1995).

<sup>2</sup> 62 FR 9115 (Feb. 28, 1997).

<sup>3</sup> 64 FR 57294 (Oct. 22, 1999).

Docket No. 2004N-0214 for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Betty B. Dorsey, Division of Freedom of Information (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6567.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background**

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The companion proposed rule and the direct final rule are substantively identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and the agency anticipates that it will receive no significant adverse comments. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document before the date of the direct final rule, to confirm the effective date of the direct final rule. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to consider all of the comments received using the usual notice-and-comment procedures.

FDA is proposing to amend its public information regulations to incorporate exemptions one, two, and three of FOIA (5 U.S.C. 552). FOIA provides that all Federal agency records shall be made

available to the public upon request, except to the extent those records are protected from public disclosure by one of nine exemptions (5 U.S.C. 552(b)) or one of three special law enforcement record exclusions (5 U.S.C. 552(c)). FDA originally issued its public information regulations implementing FOIA in 1974. As noted at the time, FDA's 1974 regulations explicitly addressed four of the nine FOIA exemptions that were then perceived to be of particular importance to the agency, those relating to trade secrets, internal memoranda, personal privacy, and investigatory files (39 FR 44602, December 24, 1974). FDA now finds it necessary to address exemption one (5 U.S.C. 552(b)(1)), given the President's designation of the Secretary of Health and Human Services to classify information under Executive Order 12958 (66 FR 64347, December 12, 2001). Because exemption two (5 U.S.C. 552(b)(2)) applies to, among other types of records, internal matters whose disclosure would risk circumvention of a legal requirement, this exemption is of fundamental importance to homeland security in light of recent terrorism events and heightened security awareness. In addition, FDA now finds that exemption three (5 U.S.C. 552(b)(3)), which incorporates the various nondisclosure provisions that are contained in other Federal statutes, is becoming increasingly important to the agency. As such, FDA is proposing to amend subpart D of its public information regulations in 21 CFR part 20 to incorporate these three exemptions.

### **III. Environmental Impact**

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

### **IV. Federalism**

FDA has analyzed this proposed 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 Executive Order and, consequently,

a federalism summary impact statement is not required.

### **V. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule simply incorporates three existing FOIA exemptions, the agency certifies that it 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 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million, adjusted annually for inflation. As noted previously, we find that this proposed rule would not have an effect of this magnitude on the economy.

### **VI. Paperwork Reduction Act of 1995**

The proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### **VII. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the

docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

#### PART 20—PUBLIC INFORMATION

1. The authority citation for part 20 continues to read as follows:

**Authority:** 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.65 is added to read as follows:

##### § 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and  
(2) In fact properly classified under such Executive order.

(b) [Reserved]

3. Section 20.66 is added to read as follows:

##### § 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules and practices of the Food and Drug Administration (FDA). Under this exemption, FDA may withhold records or information about routine internal agency practices and procedures. Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law.

4. Section 20.67 is added to read as follows:

##### § 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure if a statute specifically allows the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and

information only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld.

Dated: August 24, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–19995 Filed 9–1–04; 8:45 am]

**BILLING CODE 4160–01–S**

#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

##### 26 CFR Part 1

[REG–150562–03]

RIN 1545–BC67

##### Section 1045 Application to Partnerships; Hearing

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Change in date of public hearing; extension of time to submit outlines of oral comments.

**SUMMARY:** This document changes the date of the public hearing on the notice of proposed rulemaking that relates to the application of section 1045 of the Internal Revenue Code (Code) to partnerships and their partners. It also extends the time to submit outlines of oral comments for the hearing.

**DATES:** The public hearing originally scheduled for November 2, 2004, at 10 a.m. will be held November 9, 2004, at 10 a.m. Additional outlines of oral comments must be received by October 19, 2004.

**ADDRESSES:** The public hearing will be held in the Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC. Send submissions to: CC:PA:LPD:PR (REG–150562–03), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–150562–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the IRS Internet site at <http://www.irs.gov/regs> or via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS and REG–150562–03).

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Charlotte Chyr, (202) 622–3070, or Jian H. Grant, (202) 622–3050; concerning

submissions, the hearing, and/or placement on the building access list to attend the hearing, Sonya M. Cruse of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedures and Administration), at (202) 622–4693 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Backgrounds

A notice of proposed rulemaking and notice of public hearing, appearing in the **Federal Register** on Thursday, July 15, 2004, (69 FR 42370), announced that a public hearing on the notice of proposed rulemaking relating to the application of section 1045 of the Internal Revenue Code (Code) to partnerships and their partners would be held on November 2, 2004, in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Subsequently, the date of the public hearing has been changed to November 9, 2004, at 10 a.m. in the IRS Auditorium. Outlines of oral comments must be received by October 19, 2004.

**Cynthia E. Grigsby,**

*Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).*

[FR Doc. 04–20056 Filed 9–1–04; 8:45 am]

**BILLING CODE 4830–01–P**

#### POSTAL SERVICE

##### 39 CFR Part 111

##### Periodicals Mail Enclosures With Merchandise Sent at Parcel Post or Bound Printed Matter Rates

**AGENCY:** Postal Service.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule provides standards that would allow sample copies of authorized Periodicals publications to be mailed with merchandise mailed at Parcel Post® or Bound Printed Matter rates of postage.

**DATES:** Comments on the proposed standards must be received on or before October 4, 2004.

**ADDRESSES:** Written comments should be mailed or delivered to the Manager, Mailing Standards, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 3436, Washington DC 20260–3436. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at USPS Headquarters Library, 475 L'Enfant Plaza SW., Washington, DC 20260–0004.