included when computing net earnings from self-employment.

* * * * *

Subpart M—[Amended]

■ 6. The authority citation for subpart M of part 404 continues to read as follows:

Authority: Secs. 205, 210, 218, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 410, 418, and 902(a)(5)); sec. 12110, Pub. L. 99–272, 100 Stat. 287 (42 U.S.C. 418 note); sec. 9002, Pub. L. 99–509, 100 Stat. 1970.

■ 7. Section 404.1207 is amended by revising the second sentence of paragraph (a) to read as follows:

§ 404.1207 Divided retirement system coverage groups.

(a) *General.* * * * The States having this authority are Alaska, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Kentucky, Louisiana, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, North Dakota, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Washington, and Wisconsin.

* * * * *

[FR Doc. 05–14385 Filed 7–20–05; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 2004N–0214]

Public Information Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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 the 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.

DATES: The rule is effective August 22, 2005.

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

FDA is amending its public information regulations to incorporate exemptions one, two, and three of the FOIA (5 U.S.C. 552). The 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 the FOIA in 1974 (39 FR 44602, December 24, 1974). As noted at the time, FDA's 1974 regulations explicitly addressed four of the nine FOIA exemptions— those that were then perceived to be of particular importance to the agency and those relating to trade secrets, internal memoranda, personal privacy, and investigatory files (39 FR 44602). 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 relevant to the agency.

In the **Federal Register** of September 2, 2004, we published a direct final rule (69 FR 53615) to revise subpart D of FDA's public information regulations in part 20 (21 CFR part 20) to incorporate these three exemptions. In the same issue of the **Federal Register**, we published a companion proposed rule (69 FR 53662) to provide a procedural framework in which the rule could be finalized in the event we received any significant adverse comments regarding the direct final rule. We withdrew the direct final rule.

We received significant adverse comment on the direct final rule. Accordingly, we published a document in the **Federal Register** of January 18, 2005 (70 FR 2799), withdrawing the direct final rule. We applied the comments regarding the withdrawn direct final rule to the companion proposed rule and considered them in developing this final rule.

In addition to the changes in the proposed rule, this document also clarifies and updates § 20.82(b)(3). While this regulation had previously listed specific statutory provisions that prohibit public disclosure, this list was incomplete (e.g., it did not reference the Ethics in Government Act (5 U.S.C. app. 107(a)(2))) and was out-of-date (e.g, it listed 42 U.S.C. 263i, which is now codified at 21 U.S.C. 360nn). The amendment replaces this list of statutory provisions with a statement that FDA will not make available for public disclosure information that is prohibited from public disclosure under statute.

II. Comments on the Proposed Rule

This section discusses the two comments we received.

Issue 1: One comment suggested adding a statement that a request for records should not be denied without good cause.

Our Response: FDA is not adopting this comment because it is not necessary. Under the FOIA, an agency may not withhold a record or a portion of a record unless it falls within an FOIA exemption or exclusion. These exemptions and exclusions, including the three exemptions in the proposed rule, reflect the balance under the FOIA between providing the public with access to Government documents and the need of the Government to keep information in confidence. See, for example, *John Doe Agency* v. *John Doe Corp.*, 493 U.S. 146, 152–53 (1989)). Thus, if a record or portion of a record falls within an FOIA exemption, this in and of itself indicates that the Government has good cause for withholding it. Even when an exemption applies, however, FDA's regulations state that the agency will nonetheless make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the interests of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption (§§ 20.20(a) and 20.82(a)).

Issue 2: The second comment stated that the proposed amendments to FDA's public information regulations were unnecessarily restrictive. It went on to suggest several changes to them. Regarding proposed § 20.65 (the

exemption relating to national defense and foreign policy materials), the comment suggested that the scope of FDA's implementing regulation not include material relating to foreign policy, on the basis that public health issues should trump any foreign policy concerns. It also recommended adding the following several qualifications to the proposed regulation: (1) Any withholding must not directly conflict with any statute or judicial mandate, (2) the Executive order under which the records are classified must be constitutionally valid, and (3) the Executive order must specifically address activities of the Department of Health and Human Services (HHS).

Our Response: FDA is not adopting these comments. FDA's implementation of this exemption is consistent with exemption one of the FOIA, essentially tracking that language verbatim. It is likewise consistent with HHS' exemption one regulation (45 CFR 5.62) and the exemption one regulations issued by other agencies. FDA does not believe there is a valid need for its implementation of exemption one of the FOIA to be substantially different from exemption one of the FOIA or for its implementation to be substantially different from other agencies' implementation of the exemption. Therefore, FDA does not agree that the suggested changes are warranted.

Issue 3: Regarding proposed § 20.66 (the exemption for internal personnel rules and practices), the second comment suggested not withholding such materials from a person who is or was subject to such personnel rules and practices. The comment also suggested deleting the statement in the proposed regulation that the agency may withhold internal records whose release would help some persons circumvent the law, asserting that this language is so vague it would apply to all FDA information.

Our Response: As with all of the exemptions in FDA's public information regulations, this exemption would not apply to sharing information with current FDA employees. Therefore, a statement about employee access to FDA's internal personnel rules and practices would be unnecessary. FDA has routinely distributed this type of information to its employees through a variety of mechanisms and will continue to do so. Likewise, adding such a statement to the exemption might be confusing because it could imply that the exemptions listed in part 20 apply to sharing information with FDA employees. Regarding former employees, whether or not a particular FOIA exemption applies to a record does not depend on the identity of the person requesting the record or the nature of the person's interest in the record. See, for example, *United States Dep't of Justice* v. *Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 771 (1989). Former employees, therefore, have the same access to information under the FOIA as any other member of the public.

FDA does not agree that it should delete the statement about withholding material that would help some persons circumvent the law. This statement is consistent with exemption two of the FOIA. For example, in describing this exemption, the D.C. Court of Appeals stated that ''predominantly internal documents the disclosure of which would risk circumvention of agency statutes and regulations are protected by the so-called 'high 2' exemption.'' *(Schiller* v. *NLRB*, 964 F.2d 1205, 1207 (D.C. Cir. 1992)). The statement is also consistent with the HHS' exemption two regulation (45 CFR 5.63). For these reasons, FDA is not adopting these comments.

Issue 4: Proposed § 20.67 stated that:

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.

The second comment suggested having this exemption apply only if the statute specifically requires FDA to withhold the records and only if the statute absolutely prohibits disclosure.

Our Response: FDA is not adopting this comment. FDA believes it is appropriate to consider withholding material from public release when a statute identifies particular types of information to be withheld and when a statute sets forth criteria to guide FDA's decision on releasing and withholding material, regardless of whether the statute specifically requires FDA to withhold the material. FDA's implementation of this exemption is consistent with FOIA exemption three, HHS' exemption three regulation (45 CFR 5.64), and other agencies' exemption three regulations.

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 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 Executive order and, consequently, a federalism summary impact statement is not 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), 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final 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 final rule simply incorporates three existing FOIA exemptions, 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 requires that agencies 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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

The final 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.

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, 21 CFR part 20 is 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.

■ 5. Section 20.82 is amended by revising paragraph (b)(3) to read as follows:

§ 20.82 Discretionary disclosure by the Commissioner.

* * * * *

(b) * * *

(3) Prohibited from public disclosure under statute.

* * * * *

Dated: July 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14320 Filed 7–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct an incorrect address for the Center for Food Safety and Applied Nutrition (CFSAN). This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective July 21, 2005.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in § 101.83 (21 CFR 101.83) to reflect the correct address for CFSAN.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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 part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

§ 101.83 [Amended]

■ 2. Section 101.83 is amended in paragraph (c)(2)(ii)(*A*)(*2*) by removing ''200 C St. SW., rm. 2831, Washington, DC 20204'' and by adding in its place ''5100 Paint Branch Pkwy., College Park, MD 20740'' and in paragraph (c)(2)(ii)(*B*)(*2*)by removing ''200 C St., SW., rm. 2831, Washington, DC 20204'' and ''200 C St., SW., Washington DC'' and by adding in their place ''5100 Paint Branch Pkwy., College Park, MD 20740''.

Dated: July 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14328 Filed 7–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Roxarsone; Semduramycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting the single-ingredient roxarsone Type A medicated article that may be used to formulate three-way, combination drug Type C medicated broiler chicken feeds containing semduramicin, virginiamycin, and roxarsone under a new animal drug application (NADA) recently approved for Phibro Animal Health. FDA is also amending the animal drug regulations to reflect two roxarsone Type A medicated articles