DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 10, 14, 20, 21, 314, 350, 516, and 814

[Docket No. FDA–2011–N–0318]

Division of Freedom of Information; Change of Office Name, and Removal of Address, Telephone Number, and Fax Number; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the Agency's regulations to change the Division of Freedom of Information's (FOI's) name, and remove the address, telephone number, fax number, and Public Reading Room fax number and room number and replace them with FOI's address located on the Agency's Web site. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective November 14, 2014.

FOR FURTHER INFORMATION CONTACT: Sarah Kotler, Freedom of Information Staff, Food and Drug Administration, 301–796–8975, address available on the Agency's Web site at *http://www.fda.gov.*

SUPPLEMENTARY INFORMATION: FDA is making technical amendments in the Agency's regulations under 21 CFR parts 5, 10, 14, 20, 21, 314, 350, 516, and 814 as a result of a recent office move. The office name and address was ''Division of Freedom of Information (ELEM–1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857''. The new office name and address is listed on the Agency's Web site at *http://www.fda.gov.* The Freedom of Information Staff's new Public Reading Room number is listed on the Agency's Web site at *http://www.fda.gov.* Publication of this document constitutes final action of these changes under the Administrative Procedures Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are merely correcting nonsubstantive errors.

List of Subjects

21 CFR Part 5

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

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

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

21 CFR Part 21

Privacy.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 350

Labeling, Over-the-counter drugs.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, 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 5, 10, 14, 20, 21, 314, 350, 516, and 814 are amended as follows:

PART 5—ORGANIZATION

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

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

■ 2. In § 5.1110, revise paragraph (b) to read as follows:

§ 5.1110 FDA public information offices.

* * * * *

(b) *Freedom of Information Staff.* The Freedom of Information Staff's Public Reading Room is located at the address available on the Agency's Web site at *http://www.fda.gov.*

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PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 3. The authority citation for 21 CFR 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.

§ 10.85 [Amended]

■ 4. Section 10.85 is amended in paragraph (d)(4) by removing ''(ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the Agency's Web site at *http://www.fda.gov*)''.

§ 10.90 [Amended]

■ 5. Section 10.90 is amended in paragraph (d) by removing ''(ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the Agency's Web site at *http://www.fda.gov*)''.

§ 10.95 [Amended]

■ 6. Section 10.95 is amended in paragraphs (b)(2), (c)(2), (d)(2), (d)(7), and (d)(8) by removing ''(ELEM–1029)'' and adding in its place ''(the Freedom of Information Staff's address is available on the Agency's Web site at *http://www.fda.gov*)''.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 7. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155, Pub. L. 113–54.

§ 14.65 [Amended]

■ 8. Section 14.65 is amended in paragraph (c) by removing ''(ELEM–1029)'' and by adding in its place ''(the Freedom of Information Staff's address is available on the Agency's Web site at *http://www.fda.gov*)''.

PART 20—PUBLIC INFORMATION

■ 9. The authority citation for 21 CFR 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.

§ 20.3 [Amended]

■ 10. Section 20.3 is amended in paragraph (b) by removing ''(ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857'' and adding in its place '' at the address located on the Agency's Web site at *http://www.fda.gov.*''

■ 11. In § 20.26, revise paragraph (b) to read as follows:

§ 20.26 Indexes of certain records.

* * * * *

(b) Each such index will be made available by accessing the Agency's Web site at *http://www.fda.gov.* A printed copy of each index is available by writing or visiting the Freedom of Information Staff's address on the Agency's Web site at *http://www.fda.gov.*

§ 20.30 [Amended]

■ 12. Section 20.30 is amended in paragraph (a) by removing ''(ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857'' and adding in its place ''at the address located on the Agency's Web site at *http://www.fda.gov.*''

■ 13. In § 20.40, revise paragraph (a) to read as follows:

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff at the address on the Agency's Web site at *http://www.fda.gov* or by faxing it to the fax number listed on the Agency's Web site at *http://www.fda.gov.* All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

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§ 20.107 [Amended]

■ 14. Section 20.107 is amended in paragraph (a) by removing ''(ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857'' and adding in its place ''at the address located on the Agency's Web site at *http://www.fda.gov.*''

■ 15. In § 20.120, revise paragraph (a) to read as follows:

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Freedom of Information Staff and the Division of Dockets Management Public Reading Room are located at the same address. Both are located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. The telephone number for the Division of Docket Management is 301–827–6860; the telephone number for the Freedom of Information Staff's Public Reading Room is located at the address on the Agency's Web site at *http://www.fda.gov.* Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

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PART 21—PROTECTION OF PRIVACY

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

Authority: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

§ 21.32 [Amended]

■ 17. Section 21.32 is amended in paragraph (b)(2) in the second sentence by removing ''(HFA–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''HR–BETHPL RM7114, HFA–705, 7700 Wisconsin Ave., 7th & 8th floors, Bethesda, MD 20814'' and in the third sentence by removing ''(ELEM–1029)'' and by adding in its place ''(the Privacy Act Coordinator is part of the Freedom of Information Staff, the address for which is located on the Agency Web site at *http://www.fda.gov*)''.

§ 21.40 [Amended]

■ 18. Section 21.40 is amended in paragraph (b) by removing ''(ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857'' and by adding in its place ''(address is located on the Agency Web site at *http://www.gov.fda*)''.

§ 21.41 [Amended]

■ 19. Section 21.41 is amended in paragraphs (c) and (e) by removing ''(ELEM–1029)'' and by adding in its place ''(address is located on the Agency Web site at *http://www.gov.fda*)''.

§ 21.43 [Amended]

■ 20. Section 21.43 is amended in paragraph (a)(2) by removing ''at the address shown in § 20.30 of this chapter'' and by adding in its place ''(address is located on the Agency's Web site at *http://www.fda.gov*)''.

§ 21.52 [Amended]

■ 21. Section 21.52 is amended in paragraph (a) by removing '', Rm. 14–71, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''(see the address on the Agency's Web site at *http://www.fda.gov*)''.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 22. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 23. In § 314.53, in paragraph (e), revise the last sentence to read as follows:

§ 314.53 Submission of patent information.

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(e) * * * A request for copies of the file shall be sent in writing to the Freedom of Information Staff at the address listed on the Agency's Web site at *http://www.fda.gov.*

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PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 24. The authority citation for 21 CFR part 350 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 350.60 [Amended]

■ 25. Section 350.60 is amended by removing ''(ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857'' and adding in its place ''(address is located on the Agency's Web site at *http://www.fda.gov.*''

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 26. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 27. In § 516.157, revise paragraph (a) to read as follows:

§ 516.157 Publication of the index and content of an index listing.

(a) FDA will make the list of indexed drugs available through the FDA Web site at *http://www.fda.gov.* A printed copy can be obtained by writing to the Freedom of Information Staff or by visiting FDA's Freedom of Information Staff's Public Reading Room at the address listed on the Agency's Web site at *http://www.fda.gov.*

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PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 28. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 29. In § 814.45, revise paragraph (d)(2) to read as follows:

§ 814.45 Denial of approval of a PMA.

* * * * *

(d) * * *

(2) A request for copies of the current PMA approvals and denials document and copies of summaries of safety and effectiveness shall be sent in writing to the Freedom of Information Staff's address listed on the Agency's Web site at *http://www.fda.gov.*

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Dated: November 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26914 Filed 11–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 181

[Public Notice 8921]

RIN 1400–AD53

Publication, Coordination, and Reporting of International Agreements

ACTION: Final rule.

SUMMARY: The Department of State (''Department'') finalizes a proposed rule to add additional categories of international agreements to be exempted from the requirement to publish in the Treaties and Other International Acts Series (TIAS). The TIAS is the official treaty series of the United States and serves as evidence of the treaties, and international agreements other than treaties, in all courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States and of the several States, without any need of further proof or authentication. Certain international agreements may be exempted from publication in TIAS if the Department of State provides notice in its regulations. This rule adds three categories of international agreements that are not required to be published in TIAS.

DATES: This rule is effective on November 14, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Mattler, Treaty Affairs, Office of the Legal Adviser, Department of State, Washington, DC 20520, (202) 647–1345, or at *treatyoffice@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 1 U.S.C. 112a, the Secretary of State is required to cause to be published annually a compilation of all treaties and international agreements to which the United States is a party that were signed, proclaimed, or ''with reference to which any other final formality ha[d] been executed'' during the calendar year.

The Secretary of State, however, may determine that publication of particular categories of agreements is not required if certain criteria are met, which are listed in 1 U.S.C. 112a(b). The three categories of international agreements that are exempted by this rule (and which are now included in 22 CFR 181.8) are:

(1) Bilateral acquisition and cross servicing agreements and logistics support agreements governing the mutual exchange of logistics support, supplies and services with the military of certain countries or international organizations.

(2) Bilateral agreements relating to the provision of health care to military personnel on a reciprocal basis.

(3) Bilateral agreements for the reduction of intergovernmental debts.

Further description of these types of international agreements is included in the notice of proposed rulemaking. In addition to these changes, the Department amends 22 CFR 181.8(a)(9) to refer to the newer Executive Order dealing with classified information.

The Department of State received no comments on the proposed rule.

Regulatory Analysis

For the complete regulatory analysis regarding this rulemaking, please refer to the analysis included in the notice of proposed rulemaking, which is adopted herein.

List of Subjects in 22 CFR Part 181

Treaties.

For the reasons set forth above, 22 CFR part 181 is amended as follows:

PART 181—[AMENDED]

■ 1. The authority citation for part 181 continues to read as follows:

Authority: 1 U.S.C. 112a, 112b; and 22 U.S.C. 2651a.

■ 2. Amend § 181.8 by:

■ a. Revising paragraphs (a)(9), (12), and (13) and adding paragraphs (a)(14), (15), and (16); and

■ b. Revising paragraph (b).

The revisions and additions read as follows:

§ 181.8 Publication.

(a) * * *

(9) Agreements that have been given a national security classification pursuant to Executive Order No. 13526, its predecessors, or its successors;

* * * * *

(12) Bilateral agreements that apply to specified education and leadership development programs designed to acquaint U.S. and foreign armed forces, law enforcement, homeland security, or related personnel with limited, specialized aspects of each other's practices or operations;

(13) Bilateral agreements between aviation agencies governing specified aviation technical assistance projects for the provision of managerial, operational, and technical assistance in developing and modernizing the civil aviation infrastructure;

(14) Bilateral acquisition and cross servicing agreements and logistics support agreements;

(15) Bilateral agreements relating to the provision of health care to military personnel on a reciprocal basis; and

(16) Bilateral agreements for the reduction of intergovernmental debts.

(b) In addition to those listed in paragraph (a) of this section, the following categories of agreements will not be published in United States Treaties and Other International Agreements:

(1) Agreements on the subjects listed in paragraphs (a)(1) through (9) of this section that had not been published as of February 26, 1996;

(2) Agreements on the subjects listed in paragraphs (a)(10) through (13) of this section that had not been published as of September 8, 2006; and

(3) Agreements on the subjects listed in paragraphs (a)(14) through (16) of this section that had not been published as of November 14, 2014.

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Dated: November 5, 2014.

Michael J. Mattler,

Assistant Legal Adviser for Treaty Affairs, Department of State.

[FR Doc. 2014–27006 Filed 11–13–14; 8:45 am]

BILLING CODE 4710–08–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2014. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.