exempt (some only conditionally), the sections of the Act from which exempted, and the reasons therefor are as follows:

* * * * *

(G) Investigation and Threat Management Records—COMMERCE/DEPT–27, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid;

* * * * *

(4)(i) Exempt under 5 U.S.C. 552a(k)(5). The systems of records exempt (some only conditionally), the sections of the Act from which exempted, and the reasons therefor are as follows:

(A) Applications to U.S. Merchant Marine Academy (USMMA)—COMMERCE/MA–1;

(B) USMMA Midshipman Medical Files—COMMERCE/MA–17;

(C) USMMA Midshipman Personnel Files—COMMERCE/MA–18;

(D) USMMA Non-Appropriated Fund Employees—COMMERCE/MA–19;

(E) Applicants for the NOAA Corps—COMMERCE/NOAA–I;

(F) Commissioned Officer Official Personnel Folders—COMMERCE/NOAA–3;

(G) Conflict of lnterest Records, Appointed Officials—COMMERCE/DEPT–3;

(H) Investigative and Inspection Records—COMMERCE/DEPT–12, but only on condition that the general exemption claimed in § 4.33(b)(3) is held to be invalid;

(I) Investigative Records—Persons within the Investigative Jurisdiction of the Department COMMERCE/DEPT–13;

(J) Litigation, Claims, and Administrative Proceeding Records—COMMERCE/DEPT–14;

(K) Access Control and Identity Management System—COMMERCE/DEPT–25, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid; and

(L) Investigation and Threat Management Records—COMMERCE/DEPT–27, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid.

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2021–N–0011]

Revision to Restrictions on Shipment or Use for Human Blood and Blood Components Exceptions; Technical Amendment

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the biologics regulation to improve clarity and revise an incorrect citation. This action is being taken to ensure the accuracy and clarity of the biologics regulation.

DATES: This rule is September 7, 2021.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 22, 2015 (80 FR 29842), FDA published a final rule entitled ''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use'' (May 2015 final rule). In the May 2015 final rule, FDA amended § 610.40(h)(2)(vii) (21 CFR 610.40(h)(2)(vii)), which provides for exceptions to the restrictions on shipment or use of human blood and blood components. The May 2015 final rule included an incorrect regulatory citation in this provision.

II. Description of the Technical Amendments

In § 610.40(h)(2)(vii), as amended by the May 2015 final rule, FDA inadvertently cited § 640.65(a)(2)(ii). The reference to § 640.65(a)(2)(ii) is an incorrect citation. Accordingly, FDA is removing the reference to § 640.65(a)(2)(ii). Additionally, to improve the clarity of the regulation, we are also amending § 610.40(h)(2)(vii) to replace the reference to § 640.65(b)(2)(i) through (iv) with a reference to § 640.65(b)(2)(ii) through (iv). This amendment aligns with the preamble of the May 2015 final rule, which stated that FDA was ''removing [the citation to] § 640.65(b)(2), and replacing it with the more precise citation to § 640.65(b)(2)(ii) through (b)(2)(iv)'' (May 2015 final rule, 80 FR 29842 at 29886). FDA notes that donor protein composition assessment under § 640.65(b)(2)(i) is required for plasmapheresis procedures irrespective of whether or not the syphilis screening requirements under § 640.65(b)(2)(ii) through (iv) are applicable.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA has determined that notice and public comment are unnecessary because the amendments to the regulation provide only technical changes and are nonsubstantive.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 2. In § 610.40, revise paragraph (h)(2)(vii) to read as follows:

§ 610.40 Test requirements.

* * * * *

(h) * * *

(2) * * *

(vii) You may use Source Plasma from a donor who tests reactive by a screening test for syphilis as required under § 640.65(b)(1)(i) of this chapter, if the donor meets the requirements of § 640.65(b)(2)(ii) through (iv) of this chapter.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19220 Filed 9–3–21; 8:45 am]

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