■ 2. Section 101.5 is amended by adding paragraph(s) to read as follows:

§ 101.5 Testing terminology.

* * * * *

(s) *Stability-indicating assay.* A stability-indicating assay is a validated quantitative analytical procedure that can detect changes over time in a pertinent property of the product.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

■ 3. The authority citation for part 114 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 114.12 is revised to read as follows:

§ 114.12 Expiration date required for a serial.

Unless otherwise provided for in a Standard Requirement or filed Outline of Production, each serial or subserial of a biological product prepared in a licensed establishment shall be given an expiration date according to the dating period of the product when computed from a date no later than the date of the initiation of the first potency test of the serial or subserial. A licensed biological product shall be considered worthless under the Virus-Serum-Toxin Act after the expiration date appearing on the label.

■ 5. Section 114.13 is revised to read as follows:

§ 114.13 Determination of the dating period of a product.

The following requirements do not apply to those biological products used for diagnostic purposes.

(a) *Stability criteria.* Stability criteria include the specifications for potency at release, potency throughout the dating period, and the length of the dating period.

(b) *Stability study requirement.* The dating period of each fraction of each product shall be confirmed by conducting a stability study.

(c) *Licensure prior to completion of a stability study.* Prior to licensure, the licensee shall propose a dating period for the product based on preliminary information available about the stability of each of its fractions. If the preliminary stability information is acceptable, the product may be licensed with the provision that the proposed dating period must be confirmed by conducting a real-time stability study with a stability-indicating potency assay that can detect changes over time in the potency of the product.

(d) *Use of stability-indicating assay.* Stability studies must be conducted with a stability-indicating assay, with the following exceptions:

(1) If the potency test specified in the filed Outline of Production of a licensed product is the one stated in the regulations, that potency test may be used in place of a stability-indicating assay for that fraction.

(2) If the initial confirmation of dating study of a product in development on April 13, 2018 has an approved potency assay, that assay may be used.

(e) *Number of serials.* At least three production serials of the product shall be selected for testing in the stability study.

(f) *Testing sequences*—(1) *Initial test.* The first test in the sequence shall be as close as practical to the day of filling into final containers or the date of final formulation if the potency of the product is tested in bulk form.

(2) *Subsequent testing for in vitro assays.* (i) One test every 3 months during the first year of storage;

(ii) One test every 6 months during the second year of storage; and

(iii) One test annually thereafter throughout the proposed dating period.

(3) *Subsequent testing for in vivo assays.* One test at the end of the proposed dating period.

(g) *When to conduct a stability study.* Stability studies must be conducted for the following:

(1) Newly licensed products whose dating has not been confirmed;

(2) Licensed products with confirmed dating but a major change to the product or to the potency test has occurred; and

(3) Licensed products with confirmed dating in which a change in one or more of the stability criteria is requested.

(h) *Submitting data.* At the completion of the real-time stability study to confirm or change the dating period, the data shall be submitted to Animal and Plant Health Inspection Service for approval for filing and the approved for filing date shall be specified in section VI of the filed Outline of Production at the next revision.

(i) *Monitoring stability of the product.* For products licensed subsequent to April 13, 2018, the licensee or permittee shall submit a plan to monitor the stability of the product and the suitability of its dating period that includes regularly testing selected serials for potency during and at the end of dating.

Done in Washington, DC, this 9th day of March 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–05143 Filed 3–13–18; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

Revised Medical Criteria for Evaluating Cancer (Malignant Neoplastic Diseases)

CFR Correction

■ In Title 20 of the Code of Federal Regulations, Parts 400 to 499, revised as of April 1, 2017, on page 541, in Part 404, Subpart P, Appendix 1, under 13.02, paragraph B., the second ''OR'' is removed and under 13.03, paragraphs B.1. and B.2. are removed.

[FR Doc. 2018–05240 Filed 3–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2018–N–0399]

Medical Devices; Hematology and Pathology Devices; Classification of Lynch Syndrome Test Systems; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; correction.

SUMMARY: The Food and Drug Administration is correcting a final order entitled ''Medical Devices; Hematology and Pathology Devices; Classification of Lynch Syndrome Test Systems'' that appeared in the **Federal Register** of February 27, 2018. The document was published with the incorrect docket number. This document corrects that error.

DATES: Effective March 14, 2018.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg, 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2018 (83 FR 8355), in FR Doc. 2018–03924, on page 8355, the following correction is made: