■ 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]

BILLING CODE 3410–34–P

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]

BILLING CODE 1301–00–D

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:

1. On page 8355, in the third column, in the header of the document, the docket number is corrected to read ''FDA–2018–N–0399''.

Dated: March 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05115 Filed 3–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2017–P–5124]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Over-the-Counter Denture Repair Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order granting a petition requesting exemption from premarket notification requirements for over-the-counter (OTC) denture repair kits (Product Code EBO). These devices consist of material, such as a resin monomer system of powder and liquid glues, which is intended to be applied permanently to a denture to mend cracks or breaks. This order exempts OTC denture repair kits, class II devices, from premarket notification (510(k)). This exemption from 510(k) is immediately in effect for OTC denture repair kits. FDA is publishing this order in accordance with the section of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

DATES: This order is effective March 14, 2018. The exemption was applicable on January 31, 2018.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807 (21 CFR part 807) require persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k) to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), section 206 of which added section 510(m) to the FD&C Act, as amended on December 13, 2016, by the 21st Century Cures Act (Pub. L. 114–255). Section 510(m)(1) of the FD&C Act, requires FDA to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a device from premarket notification requirements on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-day comment period. Within 120 days after the issuance of the notice, FDA shall publish an order in the **Federal Register** setting forth the final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Class II 510(k) Exemption Guidance). That guidance can be obtained through the internet at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf* or by sending an email request to *CDRH-Guidance@fda.hhs.gov* to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Petition

On August 22, 2017, FDA received a petition requesting an exemption from premarket notification for OTC denture repair kits. (See Docket No. FDA–2017–P–5124.) These devices are currently classified under 21 CFR 872.3570, OTC denture repair kits.

In the **Federal Register** of November 20, 2017 (82 FR 55105), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by January 19, 2018. FDA received no comments.

FDA has assessed the need for 510(k) clearance for this type of device against the criteria laid out in the Class II 510(k) Exemption Guidance. Based on this review, FDA believes that premarket notification is not necessary to provide a reasonable assurance of the safety and effectiveness of the device, as long as the device complies with existing special controls. FDA agrees that the risks posed by the device and the characteristics of the device necessary for its safe and effective performance are well established. FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by certain types of routine analysis and nonclinical testing, such as those detailed in the existing special controls. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness of OTC denture repair kits. FDA responded to the petition by letter dated January 31, 2018, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Limitations of Exemption

This final order exempts from premarket notification an OTC denture repair kit. This device will remain subject to the class II special controls under 21 CFR 872.3570 and will be subject to the limitations of exemption found in 21 CFR 872.9.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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