submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, is consistent with and will effectuate the purposes of the 1996 Act.

**List of Subjects in 7 CFR Part 1212**

Administrative practice and procedure, Advertising, Consumer information, Honey Packer and Importer promotion, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1212 is amended as follows:

## PART 1212—HONEY PACKERS AND IMPORTERS RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1212 continues to read as follows:

**Authority:** 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. Section 1212.40 is revised to read as follows:

### § 1212.40 Establishment and membership.

The Honey Packers and Importers Board is established to administer the terms and provisions of this part. The Board shall have ten members, composed of three first handler representatives, two importer representatives, one importer-handler representative, three producer representatives, and one marketing cooperative representative. The importer-handler representative must import at least 75 percent of the honey or honey products they market in the United States and handle at least 250,000 pounds annually. In addition, the producer representatives must produce a minimum of 50,000 pounds of honey in the United States annually based on the best three-year average of the most recent five calendar years, as certified by producers. The Secretary will appoint members to the Board from nominees submitted in accordance with § 1212.42. The Secretary shall also appoint an alternate for each member.

■ 3. Subpart C is added to read as follows:

## Subpart C—Past Due Assessments

### § 1212.520 Late payment and interest charges for past due assessments.

(a) A late payment charge will be imposed on any first handler or importer who fails to make timely remittance to the Board of the total assessments for which they are liable. The late payment will be imposed on any assessments not received within 30 calendar days of the date when assessments are due. This one-time late payment charge will be 10 percent of the assessments due before interest charges have accrued.

(b) In addition to the late payment charge, ⅔ of 1 percent per month (or an annual rate of 8 percent) interest on the outstanding balance, including any late payment and accrued interest, will be added to any accounts for which payment has not been received within 30 calendar days of the date when assessments are due. Interest will continue to accrue monthly until the outstanding balance is paid to the Board.

Dated: March 8, 2018.

**Bruce Summers,**

*Acting Administrator.*

[FR Doc. 2018–05063 Filed 3–13–18; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 9 CFR Parts 101 and 114

**[Docket No. APHIS–2009–0028]**

**RIN 0579–AD06**

## Viruses, Serums, Toxins, and Analogous Products; Expiration Date Required for Serial and Subserials and Determination of Expiration Date of Product

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the regulations to clarify that the expiration date of a serial or subserial of a veterinary biologic should be computed from the date of the initiation of the first potency test. We are also requiring the expiration dating period (stability) of a product to be confirmed by conducting a real-time stability study with a stability-indicating assay, stability monitoring of products after licensing, and specifying a single standard for determining the expiration date for veterinary biologics

**DATES:** Effective April 13, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737–1231; (301) 851–3426.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Virus-Serum-Toxin Act regulations in 9 CFR part 114 (referred to below as the regulations), contain requirements for computing expiration dates and determining expiration dating periods (stability) for veterinary biologics. Currently, § 114.12 of the regulations requires each serial or subserial of veterinary biological products prepared in a licensed establishment to be given an expiration date, and § 114.13 provides that the expiration date for each product shall be computed from the date of the initiation of the potency test.

Prior to licensure, licensees and permittees must submit preliminary information to support the dating period shown on its labeling. Products are licensed with the provision that the dating period must be confirmed by real-time stability testing at the end of the predicted shelf life. Currently, the requirement in § 114.13 of the regulations for confirming stability is contingent upon whether a product consists of viable or non-viable organisms. For products consisting of viable organisms, each serial must be tested for potency at release and at the approximate expiration date until a statistically valid stability record has been established. For products consisting of non-viable organisms, each serial presented in support of licensure (prelicensing serials) must be tested for potency at release and at or after the dating requested. Products with satisfactory potency tests at the beginning and end of dating are considered to be efficacious throughout the requested dating period. Current science, however, considers stability estimates based on potency tests conducted at the beginning and end of the dating (a two-point profile) to be inaccurate and imprecise.[1]

To address this situation, on September 17, 2010, we published in the **Federal Register** (75 FR 56916–56919, Docket No. APHIS–2009–0028) a proposal [2] to amend the regulations by clarifying that the expiration date of a serial or subserial of a veterinary biologic should be computed from the date of the initiation of the first potency test. We also proposed to require the expiration dating period (stability) of a product to be confirmed by a real-time stability study with a stability-indicating assay; require stability

[1] Capen, R., *et al.* (2012). On the shelf life of pharmaceutical products. *AAPS PharmSciTech*. DOI: 10.1208/s12249–012–9815–2.

[2] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0028*.

monitoring of products after licensing; and specify a single standard for determining the expiration date for veterinary biologics.

We solicited comments concerning our proposal for 60 days ending November 16, 2010. We received eight comments by that date. They were from licensed manufacturers, national trade associations representing manufacturers of animal health products, a professional organization, and a private citizen. The comments are discussed below by topic.

In our review of the comments, it was evident that many commenters found the organization and wording of proposed § 114.13 to be confusing. For this reason, in addition to adopting some changes requested by commenters to the provisions, we have reorganized and reworded parts of this section to more clearly describe these requirements.

**Definition of and Requirement To Use a Stability-Indicating Assay**

We proposed to add a definition of the term *stability-indicating assay* to the regulations in part 101. One commenter stated that we did not identify the need for the addition of this definition to the regulations. Another commenter noted that we stated that product potency can degrade in a non-linear fashion and asked for clarification of why the profile of the degradation curve of a product is important in an assessment of product stability.

In the proposed rule, we noted that current science does not consider stability estimates based on potency tests conducted at the beginning and end of dating (that is, a two-point profile) to be either accurate or precise. A two point profile will determine a fixed line, but if a stability profile is non-linear, two points are inadequate to estimate the profile. Further, to estimate the precision even of a straight line would require at least three points. For this reason we proposed to amend § 114.13 to require testing of serials or subserials using a stability-indicating assay on multiple occasions throughout the predicted dating period, and to add a definition of the term *stability-indicating assay* to clarify what types of assays would be considered acceptable.

Two commenters stated that the Animal and Plant Health Inspection Service (APHIS) incorrectly cited the International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) guidelines in support of the proposed rule. The commenters stated that of the five VICH guidelines that address stability, only one, VICH GL 17, Stability Testing of Biotechnological/Biological Veterinary Medicinal Products, addresses biological products, and it only applies to well-characterized proteins and polypeptides, and their derivatives. The commenters also noted that VICH GL 17 specifically excludes conventional vaccines.

VICH is a project conducted under the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. Regulatory authorities and industry experts from Australia, Canada, and New Zealand participate as observers. The purpose of VICH is to harmonize technical requirements for veterinary medicinal products (both pharmaceuticals and biologics).

The commenters' characterization of VICH GL 17 is correct; the scope of those guidelines is limited to biotechnological/biological products and therefore they exclude conventional vaccines and numerous other products. However, the suggestion that APHIS proposed to apply the guidelines for biotechnological/biological products inappropriately to conventional vaccines is mistaken. We did not cite any VICH guidelines as a basis for the proposed rule. Rather, in the economic analysis that accompanied the proposed rule, we stated that the proposed changes were consistent with VICH recommendations, and we continue to believe that this statement is correct. We note that neither the VICH guidelines nor our regulations give specific, step-by-step directions for determining stability, nor is this rule intended to provide such directions. Instead, we state that expiration dating period (stability) of a product should be confirmed by conducting a real-time stability study with a stability-indicating assay.

Some commenters expressed concern that the proposed definition and its use in § 114.13 would require potency tests to be quantitative. The commenters noted that the potency tests for many licensed products, some of which are codified in the regulations, are not quantitative. The commenters stated that this change would force licensees to develop and validate additional assays for many products and would create conflicts with the existing regulations. One commenter stated that developing these additional assays would be expensive, would not improve the quality of the products, would divert resources from new product development, and could lead to some products being discontinued. Another commenter stated that it was unclear why non-quantitative assays are being excluded, because in many cases these assays are sufficient to determine whether or not a product has remained potent throughout the dating period.

The rule calls for a stability-indicating assay, which is one that can detect changes over time. Non-quantitative assays are not stability-indicating because they cannot detect changes over time. However, in response to these comments, we have amended § 114.13 to allow the use of codified potency tests that are not quantitative but that are included in the filed Outline of Production.

APHIS does not agree that manufacturers will need to divert resources from developing new products to develop additional assays because this final rule will not require changes to biological products that are currently licensed. In other words, the new requirement is not retroactive for prior approved products, and we believe that manufacturers will incorporate new assay development into their new product development process. We have addressed this concern in detail in the economic analysis that accompanies this final rule.

One commenter stated that in the definition of *stability-indicating assay,* the phrase ''in the pertinent properties of the product'' was too vague. The commenter suggested that the definition be revised to refer only to potency, and not to other properties of the product.

APHIS agrees with the commenter. We have amended § 114.13 to limit the requirement to potency. We have also amended the definition of *stability-indicating assay* to read ''in a pertinent property'' rather than ''the pertinent properties.'' This change clarifies that the definition is descriptive but not prescriptive, and does not impose any requirements.

Two commenters expressed concern about how the rule would apply to unlicensed products that have already completed extensive development, and stated that products in development should be treated the same as licensed products.

APHIS agrees with the commenters that products that have already completed a certain amount of development should receive some consideration. In response to this comment, we have amended § 114.13 to allow a product in development with an approved potency assay to use that assay to complete its initial confirmation of dating study.

**Diagnostic Test Kits**

One commenter asked about how the proposed rule would apply to diagnostic test kits. The commenter stated that most test kits are interpreted by qualitative means, such as a visual assessment of a reaction. The commenter stated further that a quantitative result is not needed because these test kits do not report a concentration or titer.

The provisions of this rule do not apply to diagnostic test kits. We have amended the regulatory text in § 114.13 to clarify this.

**Expiration Date Required for a Serial**

We proposed to require that the expiration date of a serial be computed from the date of the initiation of the first potency test of the serial. One commenter asked that we change this provision to allow the expiration date to be calculated from a date of or prior to the date of the initiation of the first potency test. The commenter stated that this would allow assignment of expiration dates based on manufacturing activities (such as final formulation) that precede initiation of the first potency test. The commenter further stated that in many cases, this would be a more efficient practice for a manufacturer and would also ensure that serial expiration dating does not exceed that calculated from the date of the first potency test.

APHIS agrees with the commenter. In response to this request, we have amended § 114.12 to allow the expiration date to be computed from a date no later than the date of the initiation of the first potency test.

**Determination of the Expiration Dating Period of a Product**

We proposed to require stability studies to begin on the day of filling or final formulation. Some commenters stated that the requirement to start on a single specific day was impractical and too restrictive.

In response to this comment, we have changed the requirement for testing sequences in § 114.13 to indicate that 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.

**Testing**

Some commenters stated that the testing intervals for in vitro tests in § 114.13(a) and for animal tests in § 114.13(b) require too much testing.

The sequence of intervals for in vitro tests is designed to allow estimation of the potency profile. It is typical of the contemporary approach to product shelf life assessment and has been adopted under various regulatory systems throughout the world. Furthermore, in many cases the number of serials that would be tested under the amended regulations is fewer than are used under the current regulations, so the total number of tests would be approximately the same, but the resulting data would be more informative. In response to the comments, we have clarified the provisions in the final rule for those situations when animal testing would be allowed. Specifically, we have clarified that in those cases where animal testing would be necessary, the tests would be of three serials at the start and end of the proposed dating period. This will effectively reduce the number of animal tests required as compared to the original proposal.

One commenter expressed concern that the changes would require the use of more animal tests, contrary to APHIS' commitment to reduce, refine, and replace the use of animals in testing.

APHIS disagrees that the rule will require more animal testing. On the contrary, by calling for stability-indicating assays, it discourages the use of animal tests, since most stability-indicating assays are in vitro tests conducted without animals. As explained above, however, we have clarified the requirements for situations when animal testing would be allowed.

**Statistical Methodology and Uniform Standards**

Some commenters noted that the rule does not include the statistical criteria that the agency might use to evaluate stability studies. One of the commenters stated that the proposal did not provide guidance on statistical methodology. Another commenter expressed concern that the testing requirements could be unreasonably burdensome and that if a licensee is required to have an extremely high statistical certainty, they might have to increase the potency of the product, which could lead to safety problems.

The current regulations require that licensees and permittees conduct stability studies. We proposed to amend the regulations to provide information that is lacking in the current regulations on how to conduct stability studies. We did not recommend that the potency of a product ever be increased. In fact, a more precise understanding of a vaccine's potency could allow a manufacturer to reduce the formulated potency of a vaccine while verifying that it would maintain adequate potency throughout its shelf life.

When providing guidance on methodology for implementing a codified rule, APHIS follows its usual practice of including such information in published guidance documents. Draft guidance documents are posted on the Center for Veterinary Biologics (CVB) website for comment. The policy on posting draft documents and instructions for commenting on them are described in CVB Notice No. 05–16, available online at *http://www.aphis.usda.gov/animal_health/vet_biologics/publications/notice_05_16.pdf*. We will consider all comments when formulating further guidance related to the draft document.

A commenter stated that, as proposed, the rule does not establish a uniform standard and that a number of items, including threshold values of confidence intervals or prediction intervals, interpretation of continuous or categorical data sets, and testing intervals for post-licensure monitoring vs. licensing studies should be addressed in the regulations.

APHIS disagrees with the commenter. The rule establishes a uniform standard for the design of stability studies. It does not include detailed methodological procedures for technical statistical methods which must be tailored to the data at hand. The information the commenter cited is typically covered in guidance documents. As we discussed above, these guidance documents are made available on the APHIS website for review by stakeholders before they are finalized.

One commenter stated that the requirement that manufacturers submit a plan to monitor the stability of their products and the suitability of the dating periods for those products and that the plan includes regularly testing serials for potency with stability-indicating assays is too vague.

APHIS disagrees. The expectation that product stability should be monitored by a routine ongoing program is not unusual in the modern manufacturing environment. That expectation is clearly stated in the rule; however, the rule also allows the manufacturer the flexibility to design a program that meets the needs of the particular product.

Some commenters expressed concern that the rule would prevent manufacturers from developing new products because the new requirements would require them to test every serial of a vaccine for stability.

The rule does not require that every serial of a vaccine be tested for stability. We proposed in § 114.13(a) that at least three production serials be tested. That requirement now appears in § 114.13(e) but is otherwise unchanged.

A commenter expressed concern that the rule could be applied retroactively to any licensed product at any time.

The rule does not apply retroactively. As we explained in the proposed rule, the new requirements apply to licensed products with a completed stability study only if the manufacturer makes a change to one of the stability criteria, such as the dating period, or a major change to the product or its potency test.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

*Executive Orders 12866 and 13771 and Regulatory Flexibility Act*

This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 2 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are amending the Virus-Serum-Toxin Act regulations concerning expiration dates for serials and subserials and the determination of the dating period (stability) of veterinary biological products. This rule will establish a uniform standard in stability testing for confirming the dating period and expiration date requirements. The changes will clarify and streamline the current regulations to ensure supplies of pure, safe, potent, and effective veterinary biological products.

This rule will affect all veterinary biologics licensees (manufacturers of veterinary biologics) and permittees (importers of veterinary biologics). Currently, there are approximately 100 veterinary biological establishments, including permittees. Among these veterinary biological establishments, 53 veterinary vaccine manufacturers and permittees hold 1,378 vaccine licenses.

The annual value of veterinary biological product shipments averaged between $4.3 billion and $4.4 billion, 2010–2013, having grown from $2.3 billion in 2006. U.S. exports of veterinary vaccines showed a substantial increase between 2006 and 2013, from $291 million in 2006 to $861 million in 2013. U.S. imports of veterinary vaccines are small; on average, $5.5 million of veterinary vaccines were imported annually from 2006 to 2013, resulting in a large trade surplus (exports minus imports) in the veterinary vaccine trade. In 2013, the United States was the largest exporter of veterinary vaccines in the world, followed by the Netherlands and Belgium.

This rule will help veterinary biologics manufacturers establish the best method for confirming stability. The rule aims to enable these manufacturers to take advantage of scientific advances and readily respond to changing international technical standards in the global market.

Over a 3-year period from 2012 through 2014, we received 76 reports from manufacturers that contained 192 vaccine stability studies. Based on the specific tests conducted in these stability studies, we estimate the costs associated with the current requirements, costs associated with the new requirements, and costs manufacturers actually incurred in conducting these 192 studies. We estimate that the annual total cost to the industry of stability studies under the current requirements is about $847,000 and the annual total cost to the industry under the new requirements will be about $858,000, that is, an annual cost increase of about $11,000 to the industry.

We note that the 3-year data show that manufacturers actually conducted more testing than is required under either the current or new requirements; we estimate that the manufacturers incurred costs totaling about $1,689,000 annually, which is $831,000 more than what the new requirements are estimated to cost. To provide context on industry effects, if establishments were to limit themselves to the new requirements, which are aligned with contemporary science and international standards, the industry may save about $831,000 annually in testing, an average of about $15,700 per establishment (based on 53 manufacturers). We anticipate that industry will follow the new requirements, although some firms may elect to perform more testing than required by APHIS in order to satisfy the regulatory requirements of other countries. In addition to the aforementioned annual costs, we expect that the industry will incur one-time costs that are necessary to understand the new requirements, train employees, and update policies and procedures accordingly.

According to the Small Business Administration size standards, most veterinary biologics manufacturers are small entities with no more than 500 employees. We expect that the estimated annual costs for the industry will not cause significant economic impacts for most veterinary biologics licensees and permittees, based on the estimated $11,000 annual cost increase to the industry (about $200 annual cost increase per manufacturer or permittee).

*Executive Order 12372*

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with States and local officials. (See 2 CFR chapter IV.)

*Executive Order 12988*

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the Agency's intent to occupy the field. This includes, but is not limited to, the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

*Paperwork Reduction Act*

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**List of Subjects**

*9 CFR Part 101*

Animal biologics.

*9 CFR Part 114*

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 101 and 114 as follows:

## PART 101—DEFINITIONS

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

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

■ 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: