

said Order as hereby proposed to be amended as follows:

The provisions of the proposed marketing order amending the Order contained in the proposed rule issued by the Administrator on July 19, 2018, and published in the **Federal Register** (83 FR 34953) on July 24, 2018, will be and are the terms and provisions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 956

Onions, Marketing agreements, Reporting and recordkeeping requirements.

Dated: December 11, 2018.

Bruce Summers,
Administrator, Agricultural Marketing Service.

For the reasons discussed in the preamble, 7 CFR part 956 is proposed to be amended as follows.

PART 956—SWEET ONIONS GROWN IN THE WALLA WALLA VALLEY OF SOUTHEAST WASHINGTON AND NORTHEAST OREGON

- 1. The authority citation for 7 CFR part 956 continues to read as follows:

Authority: 7 U.S.C. 601–674.

- 2. Amend § 956.20 by revising paragraph (a) to read as follows:

§ 956.20 Establishment and membership.

(a) The Walla Walla Sweet Onion Marketing Committee, consisting of seven members, is hereby established. The Committee shall consist of four producer members, two handler members, and one public member. Each member shall have an alternate who shall have the same qualifications as the member.

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- 3. Revise § 956.21 to read as follows:

§ 956.21 Term of office.

(a) Except as otherwise provided in paragraph (b) of this section, the term of office of grower and handler Committee members and their respective alternates shall be two fiscal periods beginning on June 1 or such other date as recommended by the Committee and approved by the Secretary. The terms shall be determined so that one-half of the grower membership and one-half of the handler membership shall terminate each year. Members and alternates shall serve during the term of office for which they are selected and have been qualified, or during that portion thereof beginning on the date on which they qualify during such term of office and continuing until the end thereof, or

until their successors are selected and have qualified.

(b) The term of office of the initial members and alternates shall begin as soon as possible after the effective date of this subpart. One-half of the initial industry grower and handler members and alternates shall serve for a one-year term and one-half shall serve for a two-year term. The initial as well as all successive terms of office of the public member and alternate member shall be for three years.

(c) The consecutive terms of office for all grower and handler members shall be limited to two two-year terms. There shall be no such limitation for alternate members.

■ 4. Amend § 956.28 by revising paragraph (a) to read as follows:

§ 956.28 Procedure.

(a) Four members of the Committee shall constitute a quorum, and four concurring votes shall be required to pass any motion or approve any Committee action, except that recommendations made pursuant to § 956.61 shall require five concurring votes.

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[FR Doc. 2018–27143 Filed 12–13–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 180712626–8840–01]

RIN 0694–AH61

Review of Controls for Certain Emerging Technologies

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Advance notice of proposed rulemaking (ANPRM), Extension of comment period.

SUMMARY: The Bureau of Industry and Security (BIS) is extending the comment period for its November 19, 2018, advanced notice of proposed rulemaking (ANPRM), “Review of Controls for Certain Emerging Technologies” until January 10, 2019. In response to requests received from members of the public, BIS believes it is appropriate to extend the comment period to provide interested parties additional time to submit their responses to the ANPRM.

DATES: The comment period announced in the notice that was published on November 19, 2018 (83 FR 58201) is

extended. Comments on the ANPRM must now be received by BIS on or before January 10, 2019.

ADDRESSES: You may submit comments through either of the following:

• **Federal eRulemaking Portal:** <http://www.regulations.gov>. The identification number for this rulemaking is BIS 2018–0024.

• **Address:** By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230. Refer to RIN 0694–AH61.

FOR FURTHER INFORMATION CONTACT:

Kirsten Mortimer, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce. Phone: (202) 482–0092; Fax (202) 482–3355; Email: Kirsten.Mortimer@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

On November 19, 2018 (83 FR 58201), the Bureau of Industry and Security (BIS) published an advanced notice of proposed rulemaking, “Review of Controls for Certain Emerging Technologies,” which included a comment period deadline of December 19, 2018. Since publication, BIS has received requests for additional time to submit comments. In response to those requests, BIS is extending the public comment period until January 10, 2019. A description of the specific topics and issues that BIS would like addressed is outlined in the November 19, 2018 **Federal Register** ANPRM.

Dated: December 10, 2018.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2018–27148 Filed 12–13–18; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

Withdrawal of Proposed Rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of the proposed rule on “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products” that published in the **Federal Register** of November 13, 2013. FDA is taking this action in light of concerns expressed by commenters and considerations regarding Agency resources. FDA is continuing to consider ways to improve the communication of important, newly acquired drug safety information to healthcare providers and the public and to facilitate efforts to keep drug product labeling up to date throughout the product lifecycle.

DATES: The proposed rule published November 13, 2013 (78 FR 67985), is withdrawn as of December 14, 2018.

ADDRESSES: For access to the docket, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6270, Silver Spring, MD 20993–0002, 301–796–3601, janice.weiner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and FDA regulations, the Agency makes decisions regarding the approval of marketing applications, including supplemental applications, based on a comprehensive analysis of the product’s risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (see 21 U.S.C. 355(c) and (d); 42 U.S.C. 262). All drugs have risks, and healthcare practitioners and patients must balance the risks and benefits of a drug when making decisions about medical therapy. As a drug is used more widely or under diverse conditions, new information regarding the risks and benefits of a drug may become available, and may include new risks or new information about known risks. Accordingly, all holders of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) are required to develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug

experiences to FDA (see 21 CFR 314.80(b), 314.98(a), and 600.80(b)). Application holders also must comply with applicable reporting and recordkeeping requirements, including submission of an annual report (which contains, among other things, a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, and a description of the actions the applicant has taken or intends to take as a result of this new information) and, if appropriate, proposed revisions to product labeling (see 21 U.S.C. 355(k) and 21 CFR 314.81).

When new information becomes available that causes labeling to be inaccurate, false, or misleading, all drug and biological product application holders must take steps to change the content of their product labeling in accordance with §§ 314.70, 314.97, and 601.12 (21 CFR 314.70, 314.97, and 601.12) (see 21 CFR 201.56(a)(2); see also 21 U.S.C. 331(a) and (b) and 352(a), (f), and (j)). While all drug and biological product application holders have these obligations, under current regulations, the procedures available to ANDA holders to update the labeling of generic drugs differ in certain respects from the procedures available to NDA holders and BLA holders to update product labeling. In addition, there are limitations on the procedures available to NDA holders and BLA holders to make certain updates to the Highlights of Prescribing Information of drug and biological product labeling that are subject to the content and format labeling requirements described in §§ 201.56(d) and 201.57 (21 CFR 201.56(d) and 201.57) (commonly referred to as the “Physician Labeling Rule” (PLR) format).

In the **Federal Register** of November 13, 2013 (78 FR 67985), FDA proposed to amend its regulations to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired safety-related information in advance of FDA’s review of the change by submitting a “changes being effected” (CBE–0) supplement to FDA. A CBE–0 supplement is an exception to the general requirement for FDA approval of a prior approval supplement containing revised product labeling before distribution. The proposed rule, if finalized, would have enabled ANDA holders for generic drugs to independently update and promptly distribute revised product labeling to reflect certain types of newly acquired safety-related information, even though

the revised labeling may temporarily differ from that of the corresponding reference listed drug (RLD or brand drug) upon submission of a CBE–0 supplement to FDA. FDA’s proposed revisions to its regulations to allow generic drug manufacturers to update product labeling through CBE–0 supplements in the same manner as brand drug manufacturers were intended to improve communication of important, newly acquired drug safety information to healthcare providers and the public. The proposed rule, if finalized, also would have removed the limitation on submission of CBE–0 supplements by any application holder for certain changes to the Highlights of Prescribing Information in PLR-format product labeling. For further information about these and other proposed regulatory changes described in the proposed rule, see 78 FR 67985.

FDA received numerous comments on the proposed rule from a diverse group of stakeholders. In view of requests to meet with FDA to present alternatives to the proposed regulatory changes described in the proposed rule and to promote transparency, FDA held a public meeting on March 27, 2015, at which any stakeholder had the opportunity to present or comment on the proposed rule or any alternative proposals intended to improve communication of important, newly acquired drug safety information to healthcare professionals and the public. In the February 18, 2015, document announcing the public meeting (80 FR 8577), FDA reopened the docket for the proposed rule until April 27, 2015, to receive submissions of additional written comments on the proposed rule as well as alternative proposals presented during the public meeting.

Several comments supported finalizing the rule as originally proposed. Other comments supported the goals of the proposed rule, but expressed concern that temporary labeling differences between generic drugs and the corresponding brand drug could complicate healthcare decision making. Comments in support of the proposed rule maintained that it would enhance drug safety by making healthcare practitioners and the public aware of new safety-related information about a drug more quickly. Several comments also opined that tort liability for failure to adequately warn patients of a known hazard may be an incentive for drug manufacturers to ensure that their product labeling reflects the most current safety information.

Comments in opposition to the proposed rule raised policy, legal, and cost considerations. A number of

comments asserted that generic drug application holders do not generally receive or possess all the data necessary to evaluate postmarket safety information and to support safety-related labeling changes. Comments expressed concern that additional or different warnings in generic drug labeling, even if temporary, may undermine confidence in generic drugs and their therapeutic equivalence to the brand drug. Comments throughout the healthcare delivery system also expressed concern about the confusion that might result if there were different versions of safety labeling for multiple generic versions of the same drug until FDA decided whether to approve the labeling changes proposed in the CBE–0 supplements. Several comments asserted that the proposed rule would impose significant burdens on the generic drug industry that would necessarily increase the cost of generic drugs or lead to market exit, which may increase the risk of drug shortages. However, most concerns regarding economic impact focused on the increased risk of tort litigation against generic drug manufacturers and others in the healthcare system.

II. Withdrawal of the Proposed Rule

Having reviewed the comments on the proposed rule and further considered the proposal, FDA is withdrawing the proposed rule on “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products” published in the **Federal Register** of November 13, 2013. The concerns raised in the comments reflect significant competing interests, and FDA acknowledges that the proposed rule, if finalized, would present significant potential downsides. In light of those potential downsides, the Agency does not believe that finalizing the proposed rule would be an appropriate use of Agency resources. Rather, the Agency believes that such resources would be better used on other efforts to improve the communication of important, newly acquired drug safety information to healthcare professionals and the public, as discussed in greater detail below.

The withdrawal of this proposed rule does not alter the ongoing obligation under FDA’s current regulations for all holders of marketing applications for drug and biological products—including ANDA holders—to ensure their product labeling is accurate, and not false or misleading, and to take steps to update their product labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading (see

§ 201.56(a)(2); see also 21 U.S.C. 331(a) and (b) and 352(a), (f), and (j)). This obligation serves an important public health function because new information regarding the risks and benefits of a drug may become available over time from various sources, including from postmarketing adverse drug experience reports and published literature, and updates to product labeling may be necessary.

In addition to the ongoing obligation described above, ANDA holders must generally maintain the same labeling as the RLD throughout the lifecycle of the generic drug product. ANDA holders can, however, propose certain updates to product labeling by submitting a prior approval supplement that contains adequate supporting information for the proposed change. FDA will determine whether the proposed labeling change is appropriate, and whether the labeling for the RLD and corresponding generic drug(s) should be revised. If the approval of the NDA for the RLD has been withdrawn at the NDA holder’s request because the RLD is no longer being marketed and certain other conditions are satisfied (see 21 CFR 314.150(c)), the NDA holder can no longer update labeling for the withdrawn RLD, but ANDA holders can still propose labeling updates through the submission of a prior approval supplement. In such cases, if FDA determines that the proposed labeling change is appropriate and approves the supplement, the Agency may request that other ANDA holders and any ANDA applicants relying on the same withdrawn RLD make the same updates (see FDA draft guidance for industry “Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn,” 81 FR 44883, July 11, 2016) (Draft Guidance on Updating ANDA Labeling) (Ref. 1).

As noted, the proposed rule would have removed the current prohibition against the submission of CBE–0 supplements by NDA and BLA holders to change information in the Highlights of Prescribing Information portion of drug labeling. If an NDA holder or a BLA holder seeks to submit a CBE–0 supplement to change information in the Highlights of Prescribing Information to reflect newly acquired information for any of the reasons described in § 314.70(c)(6)(iii) or § 601.12(f)(2), as applicable, the NDA holder or BLA holder can normally obtain permission to do so under the current regulation by contacting FDA. In response to an applicant’s inquiry about submission of a CBE–0 supplement for a change that would affect the

Highlights of drug labeling, FDA typically waives the limitation on submission of a CBE–0 supplement under 21 CFR 314.90 or specifically requests that the applicant proceed with a CBE–0 supplement under § 314.70(c)(6)(iii)(E) or § 601.12(f)(2)(i)(E).

FDA is continuing to consider ways to improve the communication of important, newly acquired drug safety information to healthcare professionals and the public, and to facilitate efforts to keep drug product labeling up to date throughout the product lifecycle. Although the proposed rule focused on labeling updates to reflect newly acquired information related to drug safety, we recognize that there are general challenges for keeping generic drug labeling up to date when the RLD labeling is no longer being updated, including when FDA has withdrawn approval of the NDA for reasons other than safety or effectiveness. The Agency is actively evaluating ways to facilitate the updating of generic drug labeling to help ensure that drug labeling reflects the most current information. For example, FDA’s fiscal year (FY) 2019 Budget Request includes an investment to support efforts to update generic drug labeling, with an initial focus on oncology products, as part of the Agency’s efforts to ensure that patients and their providers have access to up-to-date information to inform clinical decisions (Ref. 2). These efforts to ensure that more generic drugs have up-to-date product labeling reflecting the latest treatment information can also encourage wider adoption of generic drugs, broadening access to lower-cost alternatives to brand drugs for the American people.

The withdrawal of this proposed rule does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposal. Should we decide to undertake such rulemaking in the future, we will re-propose the action and provide new opportunities for comment. Furthermore, this proposed rule is only intended to address the withdrawal of the proposed rule on “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products” published in the **Federal Register** of November 13, 2013, and not any other pending proposals that the Agency has issued or is considering, including the Draft Guidance on Updating ANDA Labeling (Ref. 1) or the Agency’s efforts to update the labeling of certain oncology drug products under FDA’s FY2019 Budget Request (Ref. 2). If you need additional information about the subject matter of

the withdrawn proposed rule, you may review the Agency's website (<https://www.fda.gov>) for any current information on the matter.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, draft guidance for industry, "Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn," July 2016 (available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm510240.pdf>).

2. U.S. Department of Health and Human Services, Food and Drug Administration, "Fiscal Year 2019 Justification of Estimates for Appropriations Committees" (available at <https://www.fda.gov/downloads/aboutfda/reportsmanualstudies/reports/budgetreports/ucm603315.pdf>).

Dated: December 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-27098 Filed 12-13-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No.: HHS-OCR-0945-AA00]

45 CFR Parts 160 and 164

RIN 0945-AA00

Request for Information on Modifying HIPAA Rules To Improve Coordinated Care

AGENCY: Office for Civil Rights (OCR), HHS.

ACTION: Request for information.

SUMMARY: The Office for Civil Rights (OCR) is issuing this Request for Information (RFI) to assist OCR in identifying provisions of the Health Insurance Portability and Accountability Act privacy and security regulations that may impede the transformation to value-based health care or that limit or discourage coordinated care among individuals and covered entities (including hospitals, physicians, and other providers, payors, and insurers), without meaningfully contributing to the protection of the privacy or security of individuals'

protected health information. This RFI requests information on whether and how the rules could be revised to promote these goals, while preserving and protecting the privacy and security of such information and individuals' rights with respect to it.

DATES: Comments must be submitted on or before February 12, 2019.

ADDRESSES: You may send comments, identified by RIN 0945-AA00 or Docket HHS-OCR-0945-AA00, by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS-OCR-0945-AA00. Follow the instructions for sending comments.

- *Hand-Delivery or Regular, Express, or Overnight Mail:* U.S. Department of Health and Human Services, Office for Civil Rights, Attention: RFI, RIN 0945-AA00, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

Instructions: All submissions received must include "Department of Health and Human Services, Office for Civil Rights RIN 0945-AA00" for this RFI. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Further instructions are available under PUBLIC PARTICIPATION.

Docket: For complete access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and search for Docket ID number HHS-OCR-0945-AA00.

FOR FURTHER INFORMATION CONTACT: Marie Meszaros at (800) 368-1019 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Background

This RFI seeks public input on the regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹ and modified pursuant to, among other laws, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.² The HIPAA Privacy and Security Rules protect individuals' medical records and

¹ See the Administrative Simplification provisions of title II, subtitle F, of the HIPAA (Pub. L. 104-191), which added a new part C to title XI of the Social Security Act (sections 1171-1179 of the Social Security Act, 42 U.S.C. 1320d-1320d-8) and included section 264, under which HHS has adopted the HIPAA Privacy Rule.

² The HITECH Act was enacted as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5).

other individually identifiable health information created or received by or on behalf of covered entities, known as "protected health information" (PHI).³ The Privacy and Security Rules limit the circumstances under which covered entities may use and disclose PHI and require covered entities to implement safeguards to protect the privacy and security of PHI. The Privacy Rule also gives individuals rights with respect to their PHI, including the right to access their PHI and to receive adequate notice of a covered entity's privacy practices. In addition, the HIPAA Breach Notification Rule requires HIPAA covered entities to provide notification following a breach of unsecured PHI to individuals and OCR (and, in some instances, the media) and requires business associates to notify the relevant covered entities of such breaches.⁴ In this RFI, the Privacy, Security, and Breach Notification Rules will be referenced collectively as the HIPAA Rules.

OCR seeks public input on ways to modify the HIPAA Rules to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination and/or case management and to promote the transformation to value-based health care, while preserving the privacy and security of PHI. Specifically, OCR seeks information on the provisions of the HIPAA Rules that may present obstacles to, or place unnecessary burdens on, the ability of covered entities and business associates to conduct care coordination and/or case management, or that may inhibit the transformation of the health care system to a value-based health care system. Correspondingly, OCR seeks comment on modifications to the HIPAA Rules that would facilitate efficient care coordination and/or case management, and/or promote the transformation to value-based health care. OCR also broadly requests information and perspectives from regulated entities and the public about covered entities' and business associates' technical capabilities, individuals' interests, and ways to achieve these goals.

In addition, OCR seeks comment on aspects of the Privacy Rule that OCR has identified for potential modification to further these goals, specifically:

- Promoting information sharing for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize,

³ See the HIPAA Privacy and Security Rules at 45 CFR part 160 and Subparts A, C, and E of part 164.

⁴ See 45 CFR part 160 and part 164, Subparts A and D.