Joinus Freight Systems (H.K.) Limited, a.k.a., the following two aliases: –JFS Global Logistics; *and*. –Joinus Freight Systems Global Logistics Limited. Unit 07–07, 25F, Tower B, Regent Centre, 63 Wo Yi Hop Road, Kwai Chung, N.T. Hong Kong *and* Units 801–803 and 805, Park Sun Building, No. 97–107 Wo Yi Hop Road, Kwai Chung, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	81 FR 14958, 3/21/16. 83 FR [Insert FR Page Number] 9/4/2018.

* * * * *

3. On page 44826, in the table, under the country heading for Russia, the PJSC Mikron entry should read as follows:

* * * * *

PJSC Mikron, 1st Zapadniy Proezd 12/1, Zelenograd, Russia, 124460.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	81 FR 61601, 9/7/16. 83 FR [Insert FR Page Number] 9/4/2018.

* * * * *

[FR Doc. C2–2018–18766 Filed 9–11–18; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 110

[Docket No. FDA–2011–N–0920]

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is removing instruction 13 from the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food) regulation. Instruction 13 directs the **Federal Register** to remove and reserve as of September 17, 2018, the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Human Food CGMP) regulation. Removal of instruction 13 is necessary because the compliance dates for certain facilities subject to the modernized current good manufacturing practice requirements in the Preventive Controls for Human Food regulation have been extended. Retaining the Human Food CGMP regulation will maintain the status quo while these facilities prepare for compliance with the new CGMP requirements and will avoid an unintended gap in public health protection.

DATES: Effective September 12, 2018, FDA withdraws amendatory instruction 13 on page 56144 of the final rule published at 80 FR 55908 at 56144 on September 17, 2015. Submit either electronic or written comments by October 12, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0920 for ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your

comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, 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: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

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I. Background and Discussion

In the **Federal Register** of September 17, 2015, FDA published the final rule, ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (80 FR 55908; the ''rule establishing part 117''). Among other things, in the final rule establishing part 117 (21 CFR part 117), we modernized and placed in part 117, subpart B the longstanding current good manufacturing practice requirements (CGMPs) codified in part 110 (21 CFR part 110). We staggered the compliance dates for part 117 based on business size. We also instructed the **Federal Register** to remove and reserve part 110 effective September 17, 2018, the latest of the staggered compliance dates, which we treated as a conforming amendment (see instruction number 13 at 80 FR 55908 at 56144).

Subsequently, in a final rule published in the **Federal Register** of August 24, 2016 (81 FR 57784; the ''compliance date final rule''), among other things, we extended by up to 16 months the part 117 compliance dates for certain facilities, to address concerns about the practicality of compliance, consider changes to the regulatory text, and better align compliance dates across various rules. The compliance date final rule extended the part 117 compliance dates for the following establishments, as set out in table 1:

TABLE 1—FACILITIES THAT RECEIVED EXTENDED PART 117 COMPLIANCE DATES

	Compliance date announced in final rule establishing part 117	Compliance date with extension as announced in compliance date final rule
Facility solely engaged in packing and/or holding activities on produce RACs, that is:		
• a very small business	September 17, 2018	January 27, 2020.
• a small business	September 18, 2017	January 28, 2019.
• not a small or very small business	September 19, 2016	January 26, 2018.
Facility that would qualify as a secondary activities farm except for ownership of the facility, that is:		
• a very small business	September 17, 2018	January 27, 2020.
• a small business	September 18, 2017	January 28, 2019.
• not a small or very small business	September 19, 2016	January 26, 2018.
Facilities that would qualify as a farm if it did not color RACs, that is:		
a very small business	September 17, 2018	January 27, 2020.
a small business	September 18, 2017	January 28, 2019.
not a small or very small business	September 19, 2016	January 26, 2018.

A small business is a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees. A very small business is a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (*e.g.,* held for a fee). (See § 117.3.)

After issuing the compliance date final rule, FDA announced that as a matter of enforcement policy it did not intend to enforce certain part 117 requirements for certain facilities, including some of the facilities in table 1 whose compliance dates had been extended by the compliance date final rule. See the January 2018 guidance entitled ''Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs'' (*https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm590661.pdf*). The present rulemaking does not change the policies contained in this guidance.

As mentioned above, in the final rule establishing part 117 we instructed the **Federal Register** to remove and reserve part 110, effective September 17, 2018, which at the time was the latest of the staggered compliance dates. The goal was to have firms subject to the Human Food CGMP regulation until the Preventive Controls for Human Food regulation took its place, leaving no gap in public health protection. However, in the compliance date final rule we extended the compliance dates for part 117 by up to 16 months but failed to

revise the previous instruction to remove part 110. Without the current action, the small and very small facilities described in table 1 will not be subject to any CGMPs until, respectively, January 28, 2019, and January 27, 2020. However, FDA's intent always has been that part 110 would remain unchanged and in effect until all establishments have reached the date when they must be in compliance with part 117. Therefore, we are amending the rule establishing part 117 to remove the instruction to the **Federal Register** to remove and reserve part 110. We intend to remove part 110 in a separate action after all establishments have reached their compliance dates for the part 117 CGMPs.

When FDA conducts rulemaking, it normally does so using notice-and-comment procedures established under the Administrative Procedure Act (APA) and FDA regulations. These procedures allow the public an opportunity to participate in Agency rulemaking by submitting written comments on proposed rules. FDA considers these comments as it finalizes rules. (5 U.S.C. 553(b) and (c); § 10.40 (21 CFR 10.40.)) The APA, however, does not require an agency to use notice-and-comment procedures in all rulemaking. For example, the APA provides that Agencies shall not use notice-and-comment procedures, and shall proceed with a final rule, when the Agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to public interest, and incorporates the finding and a brief statement of reasons therefor in the rules issued. (5 U.S.C. 553(b)(B).) Likewise, FDA's regulations provide that the requirements of notice and public procedure do not apply when the Commissioner of Food and Drugs determines for good cause that they are impracticable, unnecessary, or contrary to the public interest, in which case, the notice issuing the regulation will state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. (§ 10.40(e)(1).) Pursuant to this regulation, FDA requests comments on the timing for the removal of part 110.

In this instance, for several reasons, FDA finds good cause for issuing this final rule without notice and comment.

Notice and comment are unnecessary because this final rule is a minor and technical repair of an obvious oversight in the compliance date final rule, maintains the CGMP regulatory status quo for industry, affirms FDA's plan for transitioning from part 110 to part 117 as outlined in the rule establishing part 117, and is not expected to generate public concern. FDA is addressing the gap in CGMP regulatory coverage from September 17, 2018, to January 27, 2020, by issuing a narrowly tailored amendment to remove instruction 13 from the rule to establish part 117. The result of this amendment will be that the part 110 CGMPs will continue in effect for establishments that have not reached their part 117 compliance date. This action will serve to correct an obvious oversight made in the compliance date final rule. FDA does not anticipate public concern with this action. The Agency previously sought public comment on its proposal to remove part 110 in coordination with the compliance dates for part 117 and received no comments that disagreed. The present continuation and planned eventual removal of part 110 is a repeat of what was previously proposed without public objection. Furthermore, it is clear from the rule establishing part 117 that we intended for facilities to remain subject to part 110 until their part 117 compliance date (80 FR 55908 at 56127). Thus, we do not believe there was ever any reasonable expectation on the part of the establishments listed in table 1 that they would not be continuously subject to CGMPs. For these various reasons, we have determined that notice and comment is unnecessary.

FDA finds further good cause for issuing this final rule without notice and comment because notice and comment are contrary to the public interest and impracticable. There could be negative public health implications if there were a temporal gap in CGMP coverage; for example, there have been outbreaks associated with the types of facilities still subject to part 110 (*e.g.,* listeria in cantaloupe). Many of the establishments listed in table 1 are not required to comply with the replacement CGMPs in part 117 until January 2019 or January 2020, depending on business size. This means that these establishments would have no applicable CGMP requirements for 4 to 16 months. CGMP requirements have existed for all human food manufacturers since at least 1970 (see 34 FR 6977) and serve as a significant basis for FDA's determination of what constitutes an insanitary food production environment that may result in food that is injurious to public health under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)), among other authorities. It would be contrary to the public interest to allow the temporal gap in CGMP coverage.

To summarize, a gap in CGMP coverage would leave FDA without a primary tool to execute its function of ensuring that food manufacturing establishments follow basic food safety practices, potentially endangering the public health, in order to provide the public an opportunity to comment on a non-controversial technical matter. For these reasons, we are issuing this amendment to the final rule establishing part 117 without prior notice and comment. (5 U.S.C. 553(b)(3)(B)).

In addition, we find good cause for this amendment to the rule establishing part 117 to become effective on the date of publication. The APA allows an effective date less than 30 days after publication as provided by the Agency for good cause found and published within the rule (5 U.S.C. 553(d)(3)). As provided at 80 FR 55908, September 17, 2015, the amendment removing part 110 was to take effect on September 17, 2018. In order to continue part 110 for an interim period, this final rule needs to be effective on or before September 16, 2018, and therefore it is not possible for this rule to take effect 30 days after publication in the **Federal Register**. As previously described, in order to prevent a gap in CGMP coverage for certain establishments, an immediate effective date is necessary to remove, before September 17, 2018, the instruction to remove and reserve part 110. Further, because the facilities' responsibility to comply with CGMP requirements remains unchanged, this rule places no burden on affected parties for which they would need a reasonable time to prepare. Therefore, the Commissioner finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) for this amendment to become effective on the date of publication.

II. Legal Authority

We are issuing this final rule removing instruction number 13 of the rule to establish part 117 under the same authority for which the rule containing instruction number 13 was originally issued. That analysis may be found in section II, ''Legal Authority,'' of the rule to establish part 117 (80 FR 55908 at 55917 to 55920).

III. Analysis of Environmental Impact

FDA has determined that the removal of instruction 13 will not change the status quo and, therefore, is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy

Act (42 U.S.C. 4321 *et seq.*). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 110

Food packaging, Foods.

■ Therefore, in FR Rule Doc. No. 2015–21920, published September 17, 2015, at 80 FR 55908–56168, amendatory instruction 13 in the third column on page 56144 is withdrawn.

Dated: September 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–19855 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 61, and 63

[EPA–R06–OAR–2016–0091; FRL–9982–62—Region 6]

New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants; Delegation of Authority to New Mexico

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; delegation of authority.

SUMMARY: The New Mexico Environment Department (NMED) has submitted updated regulations for receiving delegation and approval of a program for the implementation and enforcement of certain New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for all sources (both Title V and non-Title V sources). These updated regulations apply to certain NSPS promulgated by the EPA and amended between September 24, 2013 and January 15, 2017; certain NESHAP promulgated by the EPA and amended between January 1, 2011 and January 15, 2017; and other NESHAP promulgated by the EPA and amended between August 30, 2013 and January 15, 2017, as adopted by the NMED. The delegation of authority under this action does not apply to sources located in Bernalillo County, New Mexico, or to sources located in areas defined as Indian Country. The EPA is providing notice that it is updating the delegation of certain NSPS to NMED, and taking final action to approve the delegation of certain NESHAP to NMED.

DATES: This rule is effective on October 12, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2016–0091. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Mr. Rick Barrett (6MM–AP), (214) 665–7227; email: *barrett.richard@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Table of Contents

I. Background

On April 13, 2018, EPA published a direct final rule and accompanying proposal approving the updated delegation of authority for implementation and enforcement of NSPS and NESHAPs for all sources (both part 70 and non-part 70 sources) to the NMED. The direct final rule and proposal were published without prior proposal because EPA anticipated no relevant adverse comments. *See* 83 FR 15964 and 83 FR 16027, respectively. EPA stated in the direct final rule that if we receive relevant adverse comments by May 14, 2018, we would publish a timely withdrawal in the **Federal Register**, and all public comments received would be addressed in a subsequent final rule based on the proposed rule.

EPA received an adverse comment on May 14, 2018, and accordingly withdrew the direct final rule on June 5, 2018, pursuant to sections 111 and 112 of the CAA. *See* 83 FR 25936. The comment and our response to that comment follows below.

II. Response to Comment

Comment: EPA received an anonymous adverse comment in response to the proposed rulemaking. The comment includes several personal observations and statements critical of New Mexico's ability to maintain and oversee its air quality programs. The commenter recommends that the proposed update to New Mexico's NESHAP delegation not be approved until EPA investigates the commenter's allegations and New Mexico has addressed the alleged deficiencies. *See* Docket for the entire comment.

EPA's Response: We thank the commenter for the comment. Section 112(l) of the Act and EPA's implementing regulations at 40 CFR part 63, subpart E primarily govern EPA's actions on State requests for delegation of authority to implement and enforce the NESHAP program. CAA section 112(l)(5)(B) states that EPA shall disapprove a NESHAP program submitted by a State if we find that adequate resources are not available to implement the program. *See also* 40 CFR 63.91(d)(3)(iii). Several concerns expressed by the commenter relate to the adequacy of resources (including the lack of technically experienced and qualified staff) maintained by the NMED Air Quality Bureau. NMED provided EPA with a response to those comments that included a description of current resources and experience within the Air Quality Bureau. *See* Docket for NMED's response. In addition, consistent with 40 CFR 63.91(d)(2), New Mexico's delegation update request included a reference to its previous demonstration and a reaffirmation that the up-front approval criteria for delegation are still being met. Based on this information as well as discussions with the Compliance and Enforcement Division and the Criminal Investigation Division within EPA Region 6, we have not identified sufficient information to support the necessary finding for disapproval of the requested NESHAP