Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

[Docket No. FCIC–12–0008]

RIN 0563–AC38

Common Crop Insurance Regulations; Arizona-California Citrus Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the Common Crop Insurance Regulations, Arizona-California Citrus Crop Insurance Provisions. The intended effect of this action is to provide policy changes, to clarify existing policy provisions to better meet the needs of policyholder, and to reduce vulnerability to program fraud, waste, and abuse. The proposed changes will be effective for the 2015 and succeeding crop years.

DATES: Written comments and opinions on this proposed rule will be accepted until close of business April 22, 2013 and will be considered when the rule is to be made final.

ADDRESSES: FCIC prefers that comments be submitted electronically through the Federal eRulemaking Portal. You may submit comments, identified by Docket ID No. FCIC–12–0008, by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• Mail: Director, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, P.O. Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be not-significant for the purposes of Executive Order 12866 and, therefore, it has not been reviewed by the OMB.

Paperwork Reduction Act of 1995

Pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved byOMBunder control number 0563–0053.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Program requirements for the Federal crop insurance program are the same for all producers regardless of the size of their farming operation. For instance, all producers are required to submit an application and acreage report to establish their insurance guarantees and compute premium amounts, and all producers are required to submit a notice of loss and production information to determine the amount of an indemnity payment in the event of an insured cause of crop loss. Whether a producer has 10 acres or 1000 acres, there is no difference in the
kind of information collected. To ensure crop insurance is available to small entities, the Federal Crop Insurance Act authorizes FCIC to waive collection of administrative fees from limited resource farmers. FCIC believes this waiver helps to ensure that small entities are given the same opportunities as large entities to manage their risks through the use of crop insurance. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605).

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or action by FCIC directing the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11, or 7 CFR part 400, subpart J for determinations of good farming practices, as applicable, must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, or safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

FCIC proposes to amend the Common Crop Insurance Regulations (7 CFR part 457) by revising § 457.121 Arizona-California Citrus Crop Insurance Provisions, to be effective for the 2015 and succeeding crop years. Several requests have been made for changes to improve the insurance coverage offered, address program integrity issues, simplify program administration, and improve clarity of the policy provisions. Some of the proposed changes are a result of the United States Department of Agriculture (USDA) Acreage Crop Reporting Streamlining Initiative, which has an objective of using common standardized data and terminology to consolidate and simplify reporting requirements for farmers. USDA has made a concerted effort to standardize terms between agencies as much as possible to allow the sharing of data, thereby reducing the burden on producers in reporting their information. Many of the changes proposed in this rule are a part of that effort. As part of this initiative FCIC is proposing to change the term “crop” to “citrus fruit commodity” and to rename the “citrus fruit commodities” to be consistent with the crop names used by other USDA agencies. This change will allow information to be shared among agencies, thereby relieving producers of the burden of reporting the same information multiple times. The addition of the term “citrus fruit group” is intended to negate the impact of changes to “citrus fruit commodity” names on coverage levels, unit structure, and administrative fees. The “citrus fruit groups” for each “citrus fruit commodity” will be listed in the Special Provisions. The “citrus fruit groups” will be the basis for determining coverage levels and identifying the insured crop. These proposed changes are expected to result in no change from the current basis by which coverage levels are selected, basic units are established, and administrative fees are assessed.

To be consistent with the objectives of the Acreage Crop Reporting Streamlining Initiative, FCIC is planning to replace the category of “type” in the actuarial documents with four categories named “commodity type,” “class,” “subclass,” and “intended use.” FCIC is also planning to replace the category of “oranges” in the actuarial documents with four categories named “cropping practice,” “organic practice,” “irrigation practice,” and “interval.” Proposed changes to the Arizona-California Citrus Crop Provisions, such as replacing references to the term “type” with the term “commodity type” will provide an avenue for this transition.

The proposed changes are as follows:

1. FCIC proposes to remove the paragraph immediately preceding section 1 which refers to the order of priority in the event of a conflict. This same information is contained in the Basic Provisions. Therefore, it is duplicative and should be removed in the Arizona-California Citrus Crop Insurance Provisions.

2. Section 1—FCIC proposes to revise the definition of “crop” to allow the container size and weight to be changed by the Special Provisions. This will provide flexibility to update these figures as industry standards change. This will also allow standards to be added through the Special Provisions for any other citrus fruit commodities designated as insurable in the actuarial documents. FCIC proposes to revise the list of “citrus fruit commodities” to align with the proposed “citrus fruit commodity names.”

FCIC proposes to remove the definition of “crop” and replace it with a definition of “citrus fruit commodity” since insurable commodities are identified in the actuarial documents. FCIC proposes to replace the term “crop” with the term “citrus fruit commodity” where appropriate throughout the Crop Provisions. However, in some places the term “crop” will be changed to “insured crop” or “agricultural commodity” which are defined in the Basic Provisions or the term “crop” may be retained if using the common meaning. The current definition of “citrus fruit crop” states that the crops are listed in the Special Provisions. Adding the “citrus fruit commodity” names to the Arizona-California Crop Insurance Provisions will make it easier to determine the crops that are insurable under the Arizona-California Citrus Crop Insurance Provisions. In some cases, the new “citrus fruit commodities” will result in several of the current “crops” being combined into a single “citrus fruit commodity.” For example, the current crops “Navel,” “Valencia,” and “Sweet” will all fall under the new “citrus fruit commodity” of “oranges.” This change is being proposed because of the Acreage Crop Reporting Streamlining Initiative. This proposed change in terminology does not change the varieties of citrus that are insurable.

FCIC proposes to add the definition of “citrus fruit group.” The term “citrus fruit group” refers to a method of grouping commodity types within the “citrus fruit commodity” names of the Special Provisions for the purposes of electing coverage levels, establishing
FCIC proposes to remove the definition of “dehorning” because this term is no longer used with the revision of section 3.

FCIC proposes to add the definitions of “graft,” “interstock,” “scion,” and “topwork.” The term “topwork” is proposed to be added because it is used in a provision proposed to be added to section 6 that will require the insured trees to have reached a designated growing season after “topwork” to be insurable. The terms “graft,” “interstock,” and “scion” are proposed to be added because they are used in the proposed definition of “topwork.”

FCIC proposes to remove the definition of “variety” because all references to the term “variety” have been removed from the Crop Provisions and replaced with the term “commodity type.”

3. Section 2—FCIC proposes to revise section 2(a) to state that basic units will be established in accordance with section 1 of the Basic Provisions. The definition of basic unit in section 1 of the Basic Provisions states that basic units include all insurable acreage of the insured crop in the county on the day coverage begins for the crop year in which you have 100 percent crop share or which is owned by one person and operated by another person on a share basis. Because each “citrus fruit group” will be considered a separate insured crop, separate basic units will be established for each “citrus fruit group.” For example, under the new “citrus fruit commodity” of “oranges” all Navel oranges could be one “citrus fruit group” and all Valencia oranges could be another “citrus fruit group.” This means that all of the policyholder’s Navel orange acreage can be insured as one basic unit and all of the policyholder’s Valencia orange acreage can be insured as a separate basic unit. This proposed change in terminology will allow policyholders to keep their current unit structure under the new classification system.

FCIC proposes to revise section 2(b) by adding language to allow optional units by commodity type if allowed by the Special Provisions. Adding this language will give FCIC the flexibility to allow optional units by commodity type for some fruit commodities or citrus fruit groups where it may be appropriate, but not for others.

4. Section 3—FCIC proposes to revise section 3(a) by adding language to allow the policyholder to select separate coverage levels and price elections by “citrus fruit group.” For example, under the new citrus fruit commodity of “oranges” all Navel oranges will be grouped together as one “citrus fruit group” so that the policyholder must select the same coverage level and price election for all oranges insured under this “citrus fruit group.” These revisions to terminology will allow policyholders to continue to elect coverage levels and price elections on the same basis they currently elect coverage levels and price elections. FCIC also proposes to update the example in this section to be consistent with the proposed changes to this section.

FCIC proposes to revise section 3(b) by removing the years in the example. This will prevent the provision from appearing out of date in the future. FCIC proposes to designate the undesignated paragraph following section 3(c) as section 3(d). FCIC proposes to revise newly designated section 3(d) to add provisions to specify the adjustment to be made, if an event or action occurs that may reduce the yield potential, based on when the situation occurred. The current provision states that FCIC will reduce the yield used to establish the production guarantee, but does not provide additional details. The proposed section 3(d)(1) states that if a situation that may reduce the yield occurred before the beginning of the insurance period, the yield used to establish the production guarantee will be reduced for the current crop year regardless of whether the situation was due to an insured or uninsured cause of loss. The proposed section 3(d)(2) states that if a situation that may reduce the yield occurred after the beginning of the insurance period and the policyholder notifies the insurance provider by the production reporting date, the yield used to establish the production guarantee will be reduced for the current crop year only if the potential reduction in the yield used to establish your production guarantee is due to an uninsured cause of loss. The proposed section 3(d)(3) states that if a situation that may reduce the yield occurred after the beginning of the insurance period and the policyholder fails to notify the insurance provider by the production reporting date, an amount equal to the reduction in the yield will be added to the production count calculated in section 11(c) due to uninsured causes and the insurance provider may reduce the yield used to establish the production guarantee for the subsequent crop year. Adding these provisions removes any ambiguity regarding the consequences when situations occur that will reduce the yield potential of insured acreage.

FCIC also proposes to revise newly designated section 3(d) to remove the list of possible situations that affect yield and instead refer back to section 3(c), which contains the same information. This eliminates redundancy and is consistent with other perennial Crop Provisions, such as apples, grapes, and stonefruit.

5. Section 6—FCIC proposes to revise the introductory paragraph of section 6 by adding language to allow the insured crop to be all acreage of each “citrus fruit group.” Because the “citrus fruit groups” will be considered separate

<table>
<thead>
<tr>
<th>Citrus fruit commodity</th>
<th>Commodity type</th>
<th>Citrus fruit group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grapefruit</td>
<td>No Commodity Type Specified</td>
<td>A</td>
</tr>
<tr>
<td>Lemons</td>
<td>No Commodity Type Specified</td>
<td>B</td>
</tr>
<tr>
<td>Oranges</td>
<td>Valencia</td>
<td>C</td>
</tr>
<tr>
<td>Oranges</td>
<td>Sweet</td>
<td>D</td>
</tr>
<tr>
<td>Mandarins/Tangerines</td>
<td>Clementine</td>
<td>E</td>
</tr>
<tr>
<td>Mandarins/Tangerines</td>
<td>W. Murcott</td>
<td>F</td>
</tr>
<tr>
<td>Mandarins/Tangerines</td>
<td>Minneola</td>
<td>G</td>
</tr>
<tr>
<td>Tangelos</td>
<td>Orlando</td>
<td>H</td>
</tr>
</tbody>
</table>

The expected “commodity types” and “citrus fruit groups” are as follows:

- Oranges
- Tangelos
- Clementine
- W. Murcott
- Minneola
- Orlando
insured crops, they will be assessed separate administrative fees in accordance with section 7 of the Basic Provisions. This proposed change also allows the policyholder to elect to insure one “citrus fruit group” and not another “citrus fruit group” within the same “citrus fruit commodity.” However, since the current “citrus fruit crops” will become “citrus fruit groups,” this proposed change should not result in any changes to the administrative fees the policyholder pays or the crops the policyholder is able to elect to insure.

FCIC proposes to revise section 6(b) to clarify that the insured crop must be grown on rootstock and trees adapted to the area. The current provision states that the insured crop must be adapted to the area, but it is actually the rootstock and trees the insured crop is grown on that need to be adapted to the area.

FCIC proposes to revise section 6(e) by adding a provision to require trees to have reached the fifth growing season after topwork, unless otherwise provided in the Special Provisions or if acreage is inspected and insurance is allowed by written agreement. This provision is being proposed to address situations where established trees are “top-worked.” Since trees that have been topworked will produce little or no fruit for several years after grafting, it is not appropriate to insure the fruit these trees produce until the trees have reached the designated age.

Section 10(a) to clarify the policyholder must leave representative samples for appraisal purposes in accordance with the Basic Provisions. The Basic Provisions stipulate representative samples must be left if required by the Crop Provisions. Representative samples are necessary in order to appraise damaged production for claims purposes. The rest of the provisions in section 10 are proposed to be redesignated.

FCIC proposes to revise the newly redesignated section 10(b)(2) to clarify if the policyholder intends to claim an indemnity on any unit, the policyholder must notify the insurance provider at least 15 days prior to the beginning of harvest or immediately if damage is discovered during harvest so that the insurance provider may have an opportunity to inspect it. This change provides a timeframe for reporting damage and is consistent with revisions to other perennial crop policies.

9. Section 11—FCIC proposes to revise section 11(b) by removing the phrase “crop, or variety if applicable” and inserting the term “commodity type” in its place. This change is being proposed because “commodity type” is the category in the actuarial documents that is applicable to determining the amount of insurance for the unit. This is a proposed change in terminology and does not change how claims are settled.

FCIC proposes to revise section 11(c)(1)(iv) by removing the term “crop” and adding the term “insured crop” in its place. This change is being made to clarify that the provision is referencing the “insured crop” as defined in the Basic Provisions and section 6 of the Crop Provisions.

FCIC proposes to revise section 11(f) to clarify that this provision only applies if the policyholder elects the frost protection option. FCIC also proposes to revise this section to clarify that frost protection equipment requirements will be specified in the Special Provisions.

List of Subjects in 7 CFR Part 457

Crop insurance, Arizona-California citrus, Reporting and recordkeeping requirements.

Proposed Rule

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation proposes to amend 7 CFR part 457 effective for the 2015 and succeeding crop years as follows:
f. In section 4 by removing the phrase "(Contract Change)";
g. In section 5 by removing the phrase "(Life of Policy, Cancellation, and Termination)";
h. In section 6;
i. By revising the introductory text;
ii. In paragraph (b) by removing the phrase "grown on rootstock and trees" following the phrase "That is"; and
iii. By revising paragraph (f);
j. Revises section 7;
k. In section 8;
l. In paragraph (a) introductory text by removing the phrase "(Insurance Period)";

ii. In paragraph (a)(1) by removing the space between the number "10" and the term "day" and adding a hyphen in its place and by adding the term "insured" directly preceding the phrase "crop or to determine the condition of the grove";

iii. By revising paragraph (a)(2)(i);

iv. In paragraph (a)(2)(iii) by removing the term "citrus crops" and adding the term "citrus fruit commodities" in its place; and

v. In paragraph (b) introductory text by removing the phrase "(Insurance Period)";

k. In section 9:

i. In paragraph (a) introductory text by removing the phrase "(Cause of Loss)";

ii. In paragraph (a)(5) by removing the term "or" after the semicolon;

iii. In paragraph (a)(6) by removing the period at the end of the sentence and adding a semicolon in its place;

iv. By adding new paragraphs (a)(7) and (8); and

v. By revising paragraph (b);

l. In section 10:

i. By redesignating paragraph (a) as (b)(1);

ii. By redesignating paragraph (b) as (b)(2);

iii. By adding a new paragraph (a);

iv. By designating the introductory text as paragraph (b);

v. In the newly designated paragraph (b) by removing the phrase "(Duties in the Event of Damage or Loss)";

vi. In the newly designated paragraph (b)(2) by removing the phrase "before beginning to harvest any damaged production" and adding the phrase "at least 15 days prior to the beginning of harvest or immediately if damage is discovered during harvest" in its place; and by adding the term "insured" directly preceding the phrase "crop until after we have given you written consent to do so";

m. In section 11:

i. In paragraph (b)(1) by removing the phrase "crop, or variety, if applicable," and adding the term "commodity type" in its place;

ii. In paragraph (b)(2) by removing the phrase "crop, or variety, if applicable," and adding the phrase "commodity type" in its place;

iii. In paragraph (b)(4) by removing the phrase "variety, if applicable" and adding the phrase "commodity type" in its place;

iv. In paragraph (c)(1)(iv) by removing the term "crop" in all three places it appears and adding the term "insured crop" in its place; and

v. By revising paragraph (f).

The revisions and additions read as follows:

§ 457.121 Arizona-California citrus crop insurance provisions.

1. * * *

2. * * *

3. * * *

(a) Basic units will be established in accordance with section 1 of the Basic Provisions.

(b) * * *

(c) * * *

(d) We will reduce the yield used to establish your production guarantee, as necessary, based on our estimate of the effect of any such situation listed in section 3(c) that may occur. If you fail to notify us of any situation in section 3(c), we will reduce your production guarantee as necessary at any time we become aware of the circumstance. If the situation in 3(c) occurred:

(1) Before the beginning of the insurance period, the yield used to establish your production guarantee will be reduced for the current crop year regardless of whether the situation was due to an insured or uninsured cause of loss;

(2) After the beginning of the insurance period and you notify us by the production reporting date, the yield used to establish your production guarantee will be reduced for the current crop year only if the potential reduction in the yield used to establish your production guarantee is due to an uninsured cause of loss; or

(3) After the beginning of the insurance period and you fail to notify

* * *

Cartoon. The standard container for marketing the fresh packed citrus fruit commodity as shown below unless otherwise provided in the Special Provisions. The absence of marketing records on a carton basis, production will be converted to cartons on the basis of the following average net pounds of packed fruit in a standard packed carton unless otherwise provided in the Special Provisions.

<table>
<thead>
<tr>
<th>Container size</th>
<th>Citrus fruit commodity</th>
<th>Pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container #58</td>
<td>Oranges ..............</td>
<td>38</td>
</tr>
<tr>
<td>Container #58</td>
<td>Lemons ..............</td>
<td>40</td>
</tr>
<tr>
<td>Container #59</td>
<td>Grapefruit ...........</td>
<td>32</td>
</tr>
<tr>
<td>Container #63</td>
<td>Mandarins/Tangerines</td>
<td>25</td>
</tr>
<tr>
<td>Container #63</td>
<td>Tangelos ...........</td>
<td>25</td>
</tr>
</tbody>
</table>

Citrus fruit commodity. Citrus fruit as follows:

(1) Oranges;

(2) Grapefruit;

(3) Tangelos;

(4) Mandarins/Tangerines;

(5) Lemons; and

(6) Any other citrus fruit commodity designated in the actuarial documents.

Citrus fruit group. A designation in the Special Provisions used to identify commodity types within a citrus fruit commodity that may be grouped together for the purposes of electing coverage levels and identifying the insured crop.

Commodity type. A specific subgroup of a commodity having a characteristic or set of characteristics distinguishable from other subgroups of the same commodity.

Graft. To unite a bud or scion with a rootstock or interstock in accordance with recommended practices to form a living union.
us by the production reporting date, an amount equal to the reduction in the yield will be added to the production to count calculated in section 11(c) due to uninsured causes. We may reduce the yield used to establish your production guarantee for the subsequent crop year to reflect any reduction in the productive capacity of the trees.

6. * * *

In accordance with section 8 of the Basic Provisions, the insured crop will be all the acreage in the county of each citrus fruit group you elect to insure and for which a premium rate is provided by the actuarial documents:

* * *

(f) That is grown on trees that have reached at least 3 years of age

(1) The sixth growing season after being set out, unless otherwise provided in the Special Provisions or if we inspect and approve a written agreement to insure such acreage; or

(2) The fifth growing season after topwork, unless otherwise provided in the Special Provisions or if we inspect and approve a written agreement to insure such acreage.

7. Insurable Acreage

In lieu of the provisions in section 9 of the Basic Provisions that prohibit insurance attaching to interplanted acreage, citrus interplanted with another perennial agricultural commodity is insurable unless we inspect the acreage and determine it does not meet the requirements contained in your policy.

8. * * *

(a) * * *

(2) * * *

(i) August 31 for:

(A) Navel oranges; and

(B) Southern California lemons

(Imperial, Orange, Riverside, San Bernardino, San Diego, and Ventura Counties);

* * *

9. * * *

(a) * * *

* * *

(7) Insects, but not damage due to insufficient or improper application of pest control measures; or

(8) Plant disease, but not damage due to insufficient or improper application of disease control measures.

(b) In addition to the causes of loss excluded in section 12 of the Basic Provisions, we will not insure against damage or loss of production due to the inability to market the citrus for any reason other than actual physical damage from an insurable cause of loss specified in this section. For example, we will not pay you an indemnity if you are unable to market due to quarantine, boycott, or refusal of any person to accept production.

10. * * *

(a) In accordance with the requirements of section 14 of the Basic Provisions, you must leave representative samples in accordance with our procedures.

* * *

11. * * *

(f) If you elect the frost protection option and we determine that frost protection equipment, as specified in the Special Provisions, was not properly utilized or not properly reported, the indemnity for the unit will be reduced by the percentage of premium reduction allowed for frost protection equipment. You must, at our request, provide us records showing the start-stop times by date for each period the frost protection equipment was used.

* * *

Signed in Washington, DC, on March 11, 2013.

Brandon Willis,
Administrator, Federal Crop Insurance Corporation.

[FR Doc. 2013–06106 Filed 3–21–13; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part Chapter 1

[Docket No. FDA–2013–N–0260]

Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Request for Comments Regarding Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is inviting comments from the public on whether any potential changes to the Federal drug regulations are necessary for medical gases.

DATES: Submit electronic or written comments by May 21, 2013.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6280, Silver Spring, MD 20993–0002, 301–796–2465, christine.kirk@fda.hhs.gov; or Germaine Connolly, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., MPN2, Rockville, MD 20855, 240–276–6331, germaine.connolly@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112–144) into law. Section 1112(a) of FDASIA provides that not later than 18 months after its enactment, the Secretary of Health and Human Services, after obtaining input from medical gas manufacturers and any other interested members of the public, shall determine whether any changes to the Federal drug regulations are necessary for medical gases and submit a report regarding any such changes to the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. Section 1112(c)(l) defines “Federal drug regulations” to mean “regulations in title 21 of the Code of Federal Regulations pertaining to drugs.”

Section 1112(b) provides that if the Secretary determines that changes to the Federal drug regulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the enactment of FDASIA. FDA is opening this docket to provide the public with an opportunity to submit comments on whether any potential changes to Federal drug regulations are necessary for medical gases.

II. Opportunities for Comment on Other Medical Gas Dockets

FDASIA also added new sections regarding medical gases to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (see Title XI, Subtitle B, section 1111 of FDASIA, adding new sections 575, 576, and 577 to the FD&C Act). FDA has previously issued two other Federal Register notices related to these new sections. On November 23, 2012 (77 FR 70166), FDA issued a Federal Register notice