After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 mg/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–30051 Filed 11–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1197]

Certification Process for Designated Medical Gases; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Certification Process for Designated Medical Gases.'' The original version of this draft guidance was published by FDA on December 18, 2012. The revised draft guidance, like the original version, describes the certification process created by the Food and Drug Administration Safety and Innovation Act (FDASIA) for certain medical gases and explains how FDA plans to implement that process. In response to comments received, we have revised the draft guidance and are reissuing it in draft form to enable the public to review and comment before it is finalized.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 25, 2016. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance and attached Form 3864 by January 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2012–D–1197 for ''Certification Process for Designated Medical Gases; Revised Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Folkendt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1900; or Germaine Connolly, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8331.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 18, 2012 (77 FR 74852), FDA announced the availability of a draft guidance for industry entitled ''Certification Process for Designated Medical Gases.'' This guidance was intended to help persons or entities interested in requesting certification of a designated medical gas under the approval process for designated medical gases created by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144).

Title XI, subtitle B, of FDASIA added sections 575 and 576 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ddd and 360ddd-1), which created a certification process for designated medical gases. Specifically, section 575 of the FD&C Act provides that oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, and medical air are designated medical gases. Section 576 of the FD&C Act permits any person, beginning on January 5, 2013, to request certification of a medical gas for certain indications and describes when FDA will grant or deny these requests. The December 2012 draft guidance explained how FDA planned to implement this new certification process. Specifically, the December 2012 draft guidance described the medical gases that are eligible for certification, who should submit a certification request, what information should be submitted, and how FDA will evaluate and act on the request. The December 2012 draft guidance also described how the new certification requirement will be enforced. Finally, the draft guidance included a draft certification request form (Form FDA 3864) and form instructions.

This notice announces the availability of a revised draft guidance. In response to comments received, we have revised the discussions of labeling for final use containers (see section II of the revised draft guidance) and documentation by a person or entity that markets a designated medical gas but is not the original manufacturer or marketer of the gas (see section VI of the revised draft guidance). The December 2012 draft guidance also contained a detailed implementation timeline, which has been removed in this revised version because the dates listed in the implementation timeline have all passed. FDA has also made small revisions to improve readability and address minor technical issues. We have not made any changes to the draft certification request form (Form FDA 3864) and form instructions that were attached to the 2012 draft guidance and are attached to this revised guidance. The revised guidance is being reissued in draft form to enable the public to review and comment before it is finalized.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This revised draft guidance, when finalized, will represent the current thinking of FDA on the certification process for designated medical gases. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Certification Process for Designated Medical Gas.

Description of Respondents: Respondents to this collection of information are original manufacturers and/or marketers and downstream manufacturers and/or marketers of certain medical gas drug products.

Burden Estimate: Under section 576 of the FD&C Act and as explained in the revised draft guidance, the following information would be submitted to FDA by a person requesting certification of a designated medical gas product: A description of the medical gas for which certification is sought; the requestor's name, address, and other contact information; the name, address, and other contact information of the manufacturing facilities involved in the production of the gas; and certain affirmations that the gas meets applicable compendial standards and

that the product is manufactured in accordance with current good manufacturing practice. Requestors should make certification requests using Form FDA 3864 and include a cover letter explaining the nature of the submission (as explained in the Instructions page to the form). In certain circumstances, FDA may ask followup questions if additional information is needed from the requestor to determine whether a medical gas qualifies for certification as a designated medical gas.

If the original information submitted in connection with a certification request becomes incomplete or inaccurate at any time, including after the request has been granted, the requestor should resubmit its certification request, submitting both a complete new form and a cover letter clearly explaining the purpose of the resubmission and highlighting the updated or corrected information. All updates or corrections to the information originally submitted (other than adding a new manufacturing facility) should be submitted in this manner. If the update or change involves adding a new manufacturing facility, requestors should notify FDA of the change by submitting a ''changes being effected'' supplement under § 314.70(c) (21 CFR 314.70(c)) or § 514.8(b)(3) (21 CFR 514.8(b)(3)). The requestor should also update its registration and listing information as needed.

As explained in the revised draft guidance, section 576 of the FD&C Act permits any person to file a request for certification of a medical gas as a designated medical gas for certain indications. Based on our records, 31 requesters (''number of respondents'' in table 1, row 1) submitted 63 certification requests (''total responses'' in table 1, row 1) during 2013. Based on our familiarity with the medical gas certification process, we estimate that preparing and submitting each certification request to FDA (for original submissions and resubmissions) takes approximately 2 hours per requestor (''average burden per response'' in table 1). This estimate includes the time that some requestors may need to reply to any followup questions by FDA. For subsequent years, we expect to receive approximately five certification requests annually (including any resubmissions) (''total responses'' in table 1, row 2). All certification requests include Form FDA 3864 together with a cover letter explaining the nature of the submission.

As stated previously, requestors should notify FDA of a change that adds a new manufacturing facility by submitting a ''changes being effected'' supplement under § 314.70(c) or § 514.8(b)(3). Other manufacturing changes, *e.g.,* a change in ownership or closure of a particular manufacturing facility, should be made in accordance with § 314.70 or § 514.8 as appropriate. FDA has OMB approval under control number 0910–0001 for the submission of manufacturing supplements under § 314.70. FDA has OMB approval under control number 0910–0032 for the submission of supplements for new animal drug applications under § 514.8. As described in the revised draft guidance, requestors should also update their registration and listing information as appropriate. FDA has OMB approval under control number 0910–0045 for the submission of registration and listing information under 21 CFR part 207.

As described in the revised draft guidance, a person or entity that markets a medical gas but is neither the original manufacturer nor the original marketer should verify and document that the gas they receive is from a certified source. Documentation should include the name of the original manufacturer(s) or marketer(s) as well the applicable new drug application number or numbers associated with the gas, and the information should be verified by reference to the FDA database ''Drugs@FDA.gov.'' Each downstream customer should obtain documentation from their immediate supplier. Proper certification by a supplier or suppliers should be verified initially for existing suppliers and for new suppliers as part of a vendor qualification process. Once a new vendor or existing supplier has been qualified initially and the certification of the gas or gases confirmed, this documentation can consist of an annual letter from the immediate supplier attesting or certifying that the gas was originally manufactured at one or more firms with granted certifications. Based on our knowledge of the medical gas marketplace, we estimate that approximately 4,000 persons or entities that market a medical gas (but are neither the original manufacturer nor the original marketer) (''number of recordkeepers'' in table 2) will document and record that the gas they receive is from a certified source. We estimate that each recordkeeper will maintain approximately three records per year (''number of records per recordkeeper'' in table 2). We also estimate that it will take approximately 15 minutes per record to obtain and review the documentation (''average burden per recordkeeping'' in table 2).

Furthermore, we estimate that 3,500 persons or entities (''number of respondents'' in table 3) will provide documentation of certification. We estimate that each responder will provide approximately five disclosures per year (''frequency of disclosure'' in table 3). Lastly, we estimate that it will take approximately 15 minutes per disclosure (''hours per disclosure'' in table 3). This burden estimate includes the time required to update the disclosure annually and to provide a letter, as described in the revised draft guidance, certifying that the gas was originally manufactured at one or more firms with granted certifications.

As stated in the revised draft guidance, section 576(a)(3)(A)(ii) of the FD&C Act provides that the labeling requirements at sections 503(b)(4) and 502(f) of the FD&C Act (21 U.S.C. 353(b)(4) and 352(f), respectively) are deemed to have been met for a designated medical gas if the labeling on final use containers for the medical gas bears: (1) The information required by section 503(b)(4); (2) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and (3) appropriate directions and warnings concerning storage and handling. The revised draft guidance states that with regard to the warning statement referred to at section 576(a)(3)(A)(ii)(II) of the FD&C Act, a warning statement applicable to carbon dioxide, helium, and nitrous oxide can be found at § 201.161(a) (21 CFR 201.161(a)). However, no regulation sets forth warning statements for the other designated medical gases or for combinations of designated medical gases. The revised draft guidance states that in the absence of a regulation, FDA recommends that the labeling for final use containers containing nitrogen, medical air, carbon monoxide, or any medically appropriate combination of designated medical gases bear the warning statement set forth at § 201.161(a). The revised draft guidance also states that FDA recommends that the labeling for oxygen final use containers should convey that uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful, and that oxygen should not be used on patients who have stopped breathing unless used in conjunction with resuscitative equipment. FDA estimates that approximately 4,000 persons or entities (as described in the revised draft guidance) (''number of respondents'' in table 3) will need to include the labeling information described in the revised draft guidance

on approximately 10,250 gas containers (''frequency of disclosure'' in table 3), resulting in approximately 41,000,000 labels (''total disclosures'' in table 3). FDA expects that the labeling information currently used by industry is already consistent with the recommendations in the revised draft guidance. As a result, FDA estimates that it will take each person or entity approximately 0.1 hours (''hours per disclosure'' in table 3) to review the information to ensure that their labeling is consistent with the revised draft guidance.

FDA estimates the information collection resulting from the revised draft guidance as follows:

TABLE 1—ESTIMATED REPORTING BURDEN[1]

Form FDA 3864 and other requested information	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total hours
Certification Requests During the First Year	31	2.03	63	2	126
Certification Requests Annually After the First Year	5	1	5	2	10
Total					136

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN[1]

	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per recordkeeping (in hours)	Total hours
Verification and documentation of certified sources by persons or entities who market a medical gas but are neither the original manufacturer nor the original marketer	4,000	3	12,000	0.25 (15 minutes)	3,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

	Number of respondents	Frequency of disclosure	Total disclosures	Hours per disclosure	Total hours
Providing documentation of certification	3,500	5	17,500	0.25 (15 minutes)	4,375
Labeling required under section 576(a)(3)(A)(ii) of the FD&C Act	4,000	10,250	41,000,000	0.1 (6 minutes)	4,100,000
Total					4,104,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: *November 19, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29989 Filed 11–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4166]

Public Meeting on Patient-Focused Drug Development for Psoriasis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Psoriasis. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of psoriasis, including on daily life and patient views on treatment approaches. FDA is interested in patients' perspectives for the types of psoriasis with primarily skin symptoms (such plaque psoriasis, nail psoriasis, guttate psoriasis, etc.), patient views on treatment approaches, and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on March 17, 2016, from 10 a.m. to 6 p.m. Registration to attend the meeting must be received by March 10, 2016 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments to the public docket by May 17, 2016.

ADDRESSES: You may submit comments as follows: