combined file. CDC accepts file transmissions as individual phases or combined. In addition, each PCNASP awardee will prepare an annual aggregate hospital inventory file for transmission to CDC. The average burden of reporting hospital inventory information for each PCNASP awardee is eight hours per response.

All patient, hospital, and EMS provider data that is submitted to CDC by PCNASP awardees will be de-identified and occur through secure data systems. Proposed data elements and quality indicators may be updated over time to include new or revised items based on evolving recommendations and standards in the field to improve the quality of stroke care.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 382.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PCNASP Hospital Partners	Pre-hospital quality of care data	78	4	15/60
	Post-hospital quality of care data	20	4	15/60
	Hospital inventory data	315	1	30/60
PCNASP Awardee	Pre-hospital quality of care data	9	4	30/60
	In-hospital quality of care data	9	4	30/60
	Post-hospital quality of care data	9	4	30/60
	Hospital inventory data	9	1	8

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–30061 Filed 11–24–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–1153]

Determination That TYLENOL WITH CODEINE (Acetaminophen With Codeine Phosphate) Oral Tablets, 325 Milligrams/7.5 Milligrams, 325 Milligrams/15 Milligrams, 325 Milligrams/30 Milligrams, and 325 Milligrams/60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that TYLENOL WITH CODEINE (acetaminophen with codeine phosphate) oral tablets, 325 milligrams (mg)/7.5 mg, 325 mg/15 mg, 325 mg/30 mg, and 325 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 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, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Baluss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6278, Silver Spring, MD 20993–0002, 301–796–3469.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

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, are the subject of ANDA 85–056 held by McNeil Ortho Pharmaceuticals, Inc., and were initially approved July 9, 1976. TYLENOL WITH CODEINE is indicated for the relief of mild to moderately severe pain.

In a letter dated January 26, 1993, McNeil Ortho Pharmaceuticals, Inc. notified FDA 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 being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 7, 2015 (Docket No. FDA–2015–P–1153), under 21 CFR 10.30, requesting that the Agency determine whether 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 from sale for reasons of safety or effectiveness.

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