

The City is requesting a waiver from the Buy American provision of ARRA for one Cleanair Designs Heat Recovery Ventilator for use in the proposed activated sludge treatment building. The unit is scheduled for installation on the roof. The unit will provide ventilation and heating to the building and the design includes an air-to-air heat exchanger. The exchanger will recover energy in the exhaust air stream and transfer it to the fresh air stream, reducing the energy consumption during the heating season, with zero cross-contamination between the air streams.

The City has researched foreign and domestic manufacturers of fixed plate heat recovery ventilators and has determined that domestic manufacturers are not able to manufacture a unit that meets all the project specifications. The specifications require that the heat exchanger be constructed with a polypropylene plate. The polypropylene plate was specified because the atmosphere inside the building where the heat recovery ventilator will be installed will be very corrosive. The polypropylene plate will better resist the corrosive return air circulated through the heat exchanger than a standard aluminum plate.

An evaluation of all of the submitted documentation by EPA's technical review team supports and confirms the City's claim that there are currently no domestic manufacturers that can provide a suitable fixed plate heat recovery ventilator to meet project specifications. The consulting engineer for the City identified two domestic manufacturers in the United States. Neither of the two companies currently manufactures heat recovery units that meet all the project specifications. An independent review of the submitted documentation by EPA's national contractor found four possible domestic manufacturers. However, none of the manufacturers contacted currently provides a product that meets the specifications and project requirements. In addition, the evaluation of the supporting documentation demonstrated that foreign manufactured heat recovery ventilators are available and will be able to meet the proposed project design and specifications.

Furthermore, the purpose of the ARRA is to stimulate economic recovery by funding current infrastructure construction, not to delay or curtail entirely projects that are "shovel ready" by requiring potential SRF eligible recipients, such as the City of Lowell, MA, to revise their design standards and specifications. To curtail entirely this construction would directly conflict

with a fundamental economic purpose of ARRA, which is to create or retain jobs.

The April 28, 2009 EPA HQ Memorandum, "Implementation of Buy American provisions of Public Law 111-5, the 'American Recovery and Reinvestment Act of 2009'" ("Memorandum"), defines *reasonably available quantity* as "the quantity of iron, steel, or relevant manufactured good is available or will be available at the time needed and place needed, and in the proper form or specification as specified in the project plans and design." The same Memorandum defines "satisfactory quality" as "the quality of steel, iron or manufactured good specified in the project plans and designs."

The Municipal Assistance Unit (CMU) has reviewed this waiver request and has determined that the supporting documentation provided by the City establishes both a proper basis to specify a particular manufactured good, and that the domestically manufactured good that is currently available does not meet the design specifications for the proposed project. The information provided is sufficient to meet the following criteria listed under Section 1605(b) of the ARRA and in the April 28, 2009 Memorandum: Iron, steel, and the manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality.

The March 31, 2009 Delegation of Authority Memorandum provided Regional Administrators with the temporary authority to issue exceptions to Section 1605 of the ARRA within the geographic boundaries of their respective regions and with respect to requests by individual grant recipients.

Having established both a proper basis to specify the particular good required for this project and that this manufactured good was not available from a producer in the United States, the City of Lowell, MA is hereby granted a waiver from the Buy American requirements of Section 1605(a) of Public Law 111-5. This waiver permits use of ARRA funds for the purchase of a non-domestically manufactured fixed plate heat recovery ventilator documented in City's waiver request submittal dated July 14, 2010. This supplementary information constitutes the detailed written justification required by Section 1605(c) for waivers based on a finding under subsection (b).

Authority: Pub. L. 111-5, section 1605.

Dated: October 8, 2010.

Ira W. Leighton,
Acting Regional Administrator, EPA Region
1—New England.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-220]

Components for Evaluation of Direct-Reading Monitors for Gases and Vapors and Addendum

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft publication available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft publication for public comment. The document and its addendum are entitled, respectively, "Components for Evaluation of Direct-Reading Monitors for Gases and Vapors" and "Addendum to Components for Evaluation of Direct-Reading Monitors for Gases and Vapors: Hazard Detection in First Responder Environments." The draft documents and instructions for submitting comments can be found at: <http://www.cdc.gov/niosh/docket/review/docket220>. The document expands the 1995 method development and evaluation experimental testing methods to direct-reading monitors for gases and vapors. These *Components* are provided for laboratory users, consensus standard setting bodies, and manufacturers of direct-reading instrumentation and are compatible with the Instrumentation, Systems, and Automation Society guidelines. The addendum to the document expands the applicability of the *Components* by presenting methods to be used in evaluating direct-reading monitors for hazard detection in First Responder environments. The 1995 document, entitled "Guidelines for Air Sampling and Analytical Method Development and Evaluation," can be viewed at: <http://www.cdc.gov/niosh/docs/95-117/>.

This guidance does not have the force and effect of the law.

DATES: *Public Comment Period:*

Comments must be received by December 20, 2010.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, identified by Docket Number NIOSH-220, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

- *Facsimile:* (513) 533-8285.

- *E-mail:* nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to Docket Number NIOSH-220.

FOR FURTHER INFORMATION CONTACT:

Stanley A. Shulman, PhD., telephone (513) 841-4258, e-mail <mailto:sas2@cdc.gov>, or Amy Feng, M.S., telephone (513) 841-4128, e-mail haf0@cdc.gov, NIOSH, MS-R3, 4676 Columbia Parkway, Cincinnati, OH 45226.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2010-26221 Filed 10-18-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-P-0234]

Determination That BUSPAR (Buspirone Hydrochloride) Tablets, 10 Milligrams, 15 Milligrams, and 30 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) has determined that BUSPAR (buspirone hydrochloride) Tablets, 10 milligrams (mg), 15 mg, and 30 mg, were not withdrawn from sale

for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993-0002, 301-796-3543.

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 approved 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug. Under § 314.161(a)(2), FDA must determine whether a listed drug was withdrawn from sale for reasons of

safety or effectiveness whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, are the subject of NDA 18-731, held by Bristol-Myers Squibb, and initially approved on September 29, 1986 (10 mg strength), and April 22, 1996 (15 mg and 30 mg strengths). BUSPAR is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety. BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book. There are approved ANDAs for buspirone hydrochloride tablets, 10 mg, 15 mg, and 30 mg; these ANDAs are listed in the Orange Book and, following the discontinuation of BUSPAR, one of them was designated as the reference listed drug to which new ANDAs should refer.

Lachman Consultant Services, Inc., submitted a citizen petition dated May 4, 2010 (Docket No. FDA-2010-P-0234), under 21 CFR 10.30, requesting that the agency determine whether BUSPAR (buspirone hydrochloride) Tablets, 15 mg and 30 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 10 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing agency records, FDA has determined under § 314.161 that BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was