million N95 FFRs would be needed to protect healthcare workers during a 42-day pandemic. The rapid increase in RPD usage was apparent during the 2009 H1N1 pandemic.[e f] RPD usage may also increase beyond pandemic recommendations due to concerns about disease transmission.

Because of the potential for splashes and sprays (e.g., from a severed artery, cough, or sneeze), some facilities have selected NIOSH approved and FDA-cleared Surgical N95 respirators as the primary option for protecting healthcare workers during a pandemic. However, other NIOSH-approved RPDs might need to be considered because there may not be enough of the FDA-cleared devices to protect healthcare workers and other essential personnel during a pandemic or outbreak.

NIOSH-approved respiratory protective devices that are also FDA-cleared medical devices are widely used in surgical and non-surgical healthcare environments. There are reports [b c] that other types of NIOSH-approved RPDs that are not FDA-cleared medical devices are being used as well to protect workers in both surgical and non-surgical healthcare environments from inhalation hazards. The desirability of NIOSH incorporating additional requirements and tests in its 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance process for Surgical N95 Respirators in surgical and non-surgical healthcare environments has been mentioned during broad-based and cross-agency planning discussions for dealing with future pandemics.

NIOSH intends to use this information to consider augmenting the existing protections of 42 CFR Part 84 to incorporate requirements included in the FDA clearance process, such as fluid resistance and flammability. [b c] NIOSH is seeking public comment on the desirability of adding requirements and tests in its 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance process.

Both FDA and NIOSH require demonstration of filtration performance. The current NIOSH filtration testing requirements use non-biological aerosol based on the assumption that all particles, biological or non-biological, behave according to the same principles of aerosol physics for filtration: that is, by impaction, interception, diffusion, and electrostatic attraction. NIOSH is seeking public comment with available supporting data that either validates or disproves this assumption.

Next Steps: NIOSH will determine next steps after all comments are reviewed and assessed. NIOSH intends to provide an entry to the docket regarding next steps no later than June 30, 2014.

Dated: March 10, 2014.

John Howard,

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

[FR Doc. 2014–05611 Filed 3–13–14; 8:45 a.m.]

BILLING CODE 4163–19–P

[e] Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp. Infect. 2013 Nov; 85(3):165–9.

[f] Association of State and Territorial Health Officials. Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic. Arlington: Association of State and Territorial Health Officials; 2010.

[b] FFRs are the primary choice of respiratory protection over PAPRs or elastomeric respirators for numerous reasons. They are disposable and therefore do not require cleaning or reprocessing. They are lighter in weight and less cumbersome to don and doff as straps are generally not adjustable; nor are there any filter cartridges to be manipulated. Also, they are familiar to HCWs because of their resemblance to surgical masks commonly used in healthcare environments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0248]

Draft Guidance for Industry on Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.'' This guidance clarifies the FDA requirements and regulations pertaining to allowable excess volume in injectable vials and reinforces the importance of appropriate packaging sizes for injectable drug [1] and biological products.

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 June 12, 2014.

[1] The term *drug* used throughout this guidance refers to drugs and biological products.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Pallavi Nithyanandan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4171, Silver Spring, MD 20993–0002, 301–796–7546, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.'' FDA is concerned that injectable vial misuse, including unsafe handling and injection techniques, has led to an increase in vial contamination and an increased risk of bloodborne illness transmission between patients. This guidance clarifies the FDA requirements and regulations pertaining to allowable excess volume in injectable vials and describes when justification is needed for a proposed excess volume in an injectable drug or biological product. This guidance also discusses the importance of appropriate packaging sizes for injectable drug and biological products and recommends that labeled vial fill sizes be appropriate for the use and dosing of the drug and biological product. This guidance specifically addresses fill and packaging issues for injectable drug and biological products packaged in vials and ampules.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does

not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR parts 312 and 314 and is approved under OMB Control Numbers 0910–0014 and 0910–0001. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: March 11, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05700 Filed 3–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Cardiovascular Health and Needs Assessment in Washington, DC—Development of a Community-Based Behavioral Weight Loss Intervention

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 2, 2014, Volume 79, Issue Number 1, pages 41–42 and allowed 60-days for public comment. Public comments were received during the 60-day period. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact either: Eric Shropshire, Outreach & Research Coordinator, or Dr. Tiffany Powell-Wiley, Assistant Clinical Investigator, CPB, DIR, NHLBI, NIH, 10 Center Drive, Building 10–CRC, 5–3340, Bethesda, MD 20892, or call non-toll-free number Eric Shropshire, (301) 827–4981 or Dr. Powell-Wiley, (301) 594–3735, or Email your request, including your address to either *Eric.Shropshire@nih.gov* or *Tiffany.Powell-Wiley@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Cardiovascular Health and Needs Assessment in Washington, DC—Development of a Community-Based Behavioral Weight Loss Intervention, New, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to determine the prevalence of ideal, intermediate, and poor cardiovascular health factors based on American Heart Association (AHA)-defined goals within a church-based population in wards 5, 7, and 8 in Washington, DC. The information collected will also evaluate data from handheld devices, such as wearable physical activity monitors or digital cameras, to objectively measure physical activity and dietary intake from selected community members. This protocol will then identify technology that may be incorporated into future interventions. In addition, the collected information used will be examined for methods of referral for treatment for unrecognized hypertension, diabetes, and hypercholesterolemia in the community-based population. Social determinants of obesity, particularly environmental, cultural, and psychosocial factors that might help or hinder weight loss, will be evaluated in the population. This information from the screening and needs assessment will establish a community-based participatory research (CBPR) partnership for the future design and implementation of a church-based, behavioral weight loss intervention.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,380.

Estimated Annualized Burden Hours

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Consent Process	100	1	15/60	25