made within 60 days of receipt of the tier-one decision and should include all supporting documentation and arguments, as described in the following paragraphs.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one DR or a request for tier-two DR;
- Name and address of manufacturer inspected (as listed on FDA Form 483);
- Date of inspection (as listed on FDA Form 483);
- Date the FDA Form 483 issued (from FDA Form 483);
- Facility Establishment Identifier (FEI) Number, if available (from FDA Form 483);
- FDA employee names and titles that conducted inspection (from FDA Form 483);
- Office responsible for the inspection (e.g., district office, as listed on the FDA Form 483);
- Application number if the inspection was a preapproval inspection;
- Comprehensive statement of each issue to be resolved:
- Identify the observation in dispute:
  - Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.
  - State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of the FDA Form 483.
  - Identify possible solutions.
  - State expected outcome.
- Name, title, telephone and FAX number, and email address (as available) of manufacturer contact.

The guidance was part of the FDA initiative ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The Agency formed the Dispute Resolution Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine. The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained previously. The guidance also covers the following topics:

- The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.
- Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.
- Public availability of decisions reached during the DR process to promote consistent application and interpretation of drug quality-related regulations.

In the **Federal Register** of June 20, 2011 (76 FR 35896), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment was not related to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for Tier-One Dispute Resolution	2	1	2	30	60
Requests for Tier-Two Dispute Resolution	1	1	1	8	8
Total					68

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

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: Based on the number of requests for tier-one and tier-two dispute resolution received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 of this document provides an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

Dated: August 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–22683 Filed 9–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0530]

Mobile Medical Applications Draft Guidance; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Friday, August 12, 2011 (76 FR 50231). The document announced a public workshop entitled ''Mobile

Medical Applications Draft Guidance.'' The document was published with an outdated address in the section entitled ''Will there be transcripts of the meeting?'' This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–20574, appearing on page 50231 in the **Federal Register** of Friday, August 12, 2011, the following correction is made:

1. On page 50233, in the second column, under the section entitled ''Will there be transcripts of the meeting?'' the address for the Division of Freedom of Information is corrected to read ''Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.''

Dated: August 31, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–22674 Filed 9–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Fully Automated Bone Mineral Densitometry on Routine CT Scans

Description of Technology: The invention relates to an improved system for measuring bone mineral density (BMD). BMD measurement is an important tool for the diagnosis of osteopenia- and osteoporosis-related fractures, a significant national health problem primarily affecting the elderly and women after menopause. More specifically, the invention relates to an algorithm and software for fully automating BMD measurement, using routine CT data and eliminating the need for a reference phantom or a specialized imaging protocol. The current standard methods not only require reference phantom to be placed underneath the patient and a specialized imaging protocol, but they also require manually placed regions of interest (ROI) to identify the appropriate bone structures. The benefit of the automated method provided in the invention is that with this system BMD measurement will be available for every patient with chest/abdominal CT scan (millions are done every year) so that the potential low bone mineral density can be discovered.

Potential Commercial Applications:

• The technique can be integrated to a CT scanner to provide automated measurement of BMD for every CT scan.

• The technique can be integrated into PACS (Picture Archiving and Communication Systems) to report BMD at the time of image interpretation by the radiologist or clinician.

Competitive Advantages: The technique can be readily integrated to existing medical imaging systems such as CT scanners (to provide BMD measurement with every CT scan) or PACS (to report BMD at the time of image interpretation).

Development Stage:

• Prototype

• In vivo data available (human)

Inventors: Ronald M. Summers *et al.* (NIH–CC)

Publication: Summers RM, et al. Feasibility of simultaneous computed tomographic colonography and fully automated bone mineral densitometry in a single examination. J Comput Assist Tomogr. 2011 Mar–Apr;35(2):212–216. [PMID 21412092]

Intellectual Property: HHS Reference No. E–218–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Filovirus Vaccines and Diagnostics Based on Glycoprotein-Fc Fusion Proteins

Description of Technology: Ebola virus is a member of the Filoviridae, a family of viruses classified as ''Category A'' bioterrorism agents that cause severe hemorrhagic fever in humans and nonhuman primates with high morbidity and mortality rates up to 90%. This invention provides an efficacious Filovirus subunit vaccine based on a recombinant protein consisting of the extracellular domain of the Filovirus glycoprotein fused to an Fc Fragment of human immunoglobulin (FiloGP-Fc). Vaccination with FiloGP-Fc elicited humoral and cellular immunity against Filoviruses. The FiloGP-Fc vaccine induced antibodies that bound and neutralized replication-competent recombinant G-deleted Vesicular Stomatitis Virus containing the Filovirus GP (rVSV-FiloGP), and protected animals against Filovirus lethal challenge. Also described are cellular and humoral immunity tests as well as rVSV-FiloGP neutralization tests to evaluate anti-Filovirus immune responses in individuals.

Potential Commercial Applications:

• Vaccines for protection against infections by Ebola Virus and other Filoviruses.

• Diagnostic tests for cellular and humoral immunity based on FiloGP-Fc and rVSV-FiloGP to evaluate anti-Filovirus immune responses in vaccinated and infected animals and individuals.

Competitive Advantages: Filovirus vaccine candidates based on virus-like particles and virus vectors are currently under development by others. However, efficacious subunit vaccines have not yet been developed. The FiloGP-Fc fusion protein described in this invention has the advantage of resembling the native glycoprotein expressed at the surface of cells and viral particles. Thus, in addition to vaccines, the soluble FiloGP-Fc fusion proteins are ideal substrates to evaluate immune responses in animals and vaccinees.

Development Stage:

• Early-stage

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Geraldo Kaplan (FDA), Krishnamurthy Konduru (FDA), *et al.*

Publication: Konduru K, *et al.* Ebola virus glycoprotein Fc fusion protein confers protection against lethal challenge in vaccinated mice. Vaccine 2011 Apr 5;29(16):2968–2977. [PMID 21329775]