TABLE 1—TOTAL ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Food Safety and Applied Nutrition (Three different product categories)					
	386	2	772	1.5	1,158
	247	47	11,609	2	23,218
	337	1	337	0.5	169
Total	15,653		27,401		50,942

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

Dated: September 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25009 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0477]

Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public hearing to obtain input on specific issues and challenges associated with the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act establishes an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to, or "interchangeable" with, an FDA-licensed biological product. The purpose of this public hearing is to create a forum for interested stakeholders to provide input regarding the agency's implementation of the statute. FDA will take the information it obtains from the public hearing into account in its implementation of the BPCI Act.

DATES: The public hearing will be held November 2 and 3, 2010, from 8:30 a.m. to 4:30 p.m. Individuals who wish to present at the public hearing must register on or before October 11, 2010. Section III of this document provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until December 31, 2010.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31, Rm. 1503, Silver Spring, MD 20993.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Identify comments with the corresponding docket number found in brackets in the heading of this document.

Transcripts of the public hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public hearing (see Section VI of this document).

A live webcast of this public hearing will be viewable at the following Web addresses on the days of the public hearing: *http://www.fda.gov/Drugs/NewsEvents/ucm221688.htm.* A video record of the public hearing will be available at the same Web addresses for 1 year.

FOR FURTHER INFORMATION CONTACT: Sandra J. Benton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993, 301–796–1042, FAX: 301–847–3529, *E-mail: biosimilarspublicmtg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product (see sections 7001 through 7003 of the BPCI Act).

The objectives of the BPCI Act are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (commonly referred to as the "Hatch-Waxman Act"), which established abbreviated pathways for the approval of drug products under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The BPCI Act aligns with FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing. The implementation of an abbreviated approval pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and often more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, describes the general requirements for an application for a proposed biosimilar biological product and an application or a supplement for a proposed interchangeable biological product.

A biological product may be demonstrated to be "biosimilar" to a biological reference product based upon data derived from analytical studies, animal studies, and a clinical study or studies if the product is shown to be highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and if there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.

To meet the higher standard of "interchangeability," a product must demonstrate that it can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider.

The BPCI Act also includes, among other provisions: A 12-year period of marketing exclusivity from the date of first licensure of the reference product, during which approval of a 351(k) application referencing that product cannot be made effective; an exclusivity period for the first biological product submitted in a 351(k) application that has been determined to be interchangeable with the reference product for any condition of use, during which a second or subsequent biological product may not be determined interchangeable to that reference product; and a transition provision for protein products that have been or will be approved under section 505 of the FD&C Act (21 U.S.C. 355) prior to March 23, 2020.

The BPCI Act also requires that FDA develop recommendations to present to Congress with respect to a user fee program for biosimilar and interchangeable biological products. Such recommendations must address the goals for the process of reviewing 351(k) applications, and plans for meeting those goals, for fiscal years (FY) 2013 to 2017. In developing such recommendations, FDA is required to consult with the Committee on Health, Education, Labor, and Pensions of the Senate; the Committee on Energy and Commerce of the House of Representatives; scientific and academic experts; healthcare professionals; representatives of patient and consumer advocacy groups; and regulated industry.

The BPCI Act also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHS Act; these procedures do not involve FDA and are not within the scope of this public hearing.

II. Purpose and Scope of the Public Hearing

The purpose of this part 15 hearing is to receive information and comments from a broad group of stakeholders, such as healthcare professionals, healthcare institutions, manufacturers of biomedical products, interested industry and professional associations, patients and patient associations, third party payers, current and prospective biological license application (BLA) and new drug application (NDA) holders, and the public, regarding implementation of the BPCI Act.

To prepare to begin negotiations with regulated industry regarding a user fee program, FDA must identify which companies and trade associations would be affected by a user fee program for biosimilar and interchangeable biological products (*i.e.,* a company likely to submit an application for approval of a biosimilar or interchangeable biological product).

The purpose of this public hearing is to create a forum for interested stakeholders to provide input regarding the agency's implementation of the statute concerning the following issues, among others: Scientific and technical factors related to a determination of biosimilarity or interchangeability; the type of information that may be used to support a determination of biosimilarity or interchangeability; development of a framework for optimal pharmacovigilance for biosimilar and interchangeable biological products; scope of the revised definition of a "biological product"; priorities for guidance development; scientific and technical factors related to reference product exclusivity; scientific and technical factors that may inform the agency's interpretation of "product class" as it relates to available regulatory pathways for certain protein products during the 10-year transition period following enactment of the BPCI Act; and the establishment of a user fee program for biosimilar and interchangeable biological products.

FDA is particularly interested in obtaining information and public comment on the following issues, although any comments on any issues related to biosimilar or interchangeable biological products are welcome.

A. Biosimilarity

Section 351(k) of the PHS Act as set forth in the BPCI Act requires, among other things, that an application for a proposed biosimilar product include information demonstrating that the proposed product is biosimilar to a reference product based upon data derived from:

- Analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
- Animal studies (including the assessment of toxicity); and
- A clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed.

The BPCI Act provides that FDA may determine, at its discretion, that an element described previously is unnecessary in a 351(k) application.

FDA seeks comments on the following issues:

1. What scientific and technical factors should the agency consider in determining whether the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components?
2. What scientific and technical factors should the agency consider in determining the appropriate analytical, animal, and clinical study or studies to assess the nature and impact of actual or potential structural differences between the proposed biosimilar product and the reference product?
3. What range of structural differences between a proposed biosimilar product and the reference product is consistent with the standard "highly similar" and may be acceptable in a 351(k) application if the applicant can demonstrate the absence of any clinically meaningful differences between the proposed biosimilar product and the reference product?
4. Under what circumstances should the agency consider finding that animal studies or a clinical study or studies are "unnecessary" for submission of a 351(k) application?

B. Interchangeability

Section 351(k)(4) of the PHS Act requires that an application for a proposed interchangeable product contain information sufficient to demonstrate:

- The biological product is biosimilar to the reference product; and
- The biological product can be expected to produce the same clinical result as the reference product in any given patient; and
- For a biological product that is administered more than once to an

individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

FDA seeks input on the following issues related to interchangeability:

1. What factors should the agency consider in determining whether a proposed interchangeable biological product can be "expected to produce the same clinical result as the reference product in any given patient?"

2. What factors should the agency consider in evaluating the potential risk related to alternating or switching between use of the proposed interchangeable biological product and the reference product or among interchangeable biological products?

C. Patient Safety and Pharmacovigilance

The agency considers the safety of patients who are taking any medical products to be of paramount importance. To that end and to protect each individual patient, the agency is developing a framework for optimal pharmacovigilance for biosimilar and interchangeable products that is informed by our current experience and industry best practices. In the interest of patient safety and for the purpose of pharmacovigilance, the agency must be able to distinguish between a reference product, a related biological product that has not been demonstrated to be biosimilar, a biosimilar product, and an interchangeable product.

FDA seeks comments on the following issues:

1. What factors unique to proposed biosimilar or interchangeable biological products and their use should the agency consider in developing its pharmacovigilance program for such products?

2. What approaches can be undertaken by the agency, industry, or health care community to ensure appropriate pharmacovigilance for biosimilar and interchangeable products?

3. If each product were given a unique nonproprietary name, should a distinguishing prefix or suffix be added to the nonproprietary name for a related biological product that has not been demonstrated to be biosimilar, a biosimilar product, or an interchangeable product to facilitate pharmacovigilance? What factors should be considered to reduce any negative impact on the healthcare delivery system related to unique nonproprietary names for highly similar biological products?

4. What safeguards should the agency consider to assist the healthcare community when prescribing, administering, and dispensing biological products to prevent unsafe substitution of biological products?

5. What are some mechanisms that FDA may consider to communicate findings that a particular product is or is not biosimilar to or interchangeable with a given reference product?

D. The Use of Supportive Data and Information

The BPCI Act provides that an application for the licensure of a biosimilar or interchangeable product: Shall include publicly available information regarding the Secretary's (Department of Health and Human Services) previous determination that the reference product is safe, pure, and potent; and may include any additional information in support of the application, including publicly available information with respect to the reference product or another biological product (section 351(k)(2)(A)(iii) of the PHS Act).

The BPCI Act defines the term "reference product" to mean "the single biological product licensed under [section 351(a)] against which a biological product is evaluated in an application submitted under [section 351(k)]." Accordingly, section 351(k) requires that an applicant demonstrate biosimilarity to and or interchangeability with a reference product licensed by FDA (as distinguished from a biological product licensed by a foreign regulatory authority).

The agency is aware that some prospective biosimilar sponsors have conducted animal and/or clinical studies to support regulatory approval in another jurisdiction using a non-U.S.-licensed biological product as a comparator. To avoid duplicative animal and human testing, sponsors may wish, to the extent permissible, to rely on these studies to support a 351(k) application.

FDA seeks comments on the following issue: From a scientific perspective, to what extent, if any, should animal or clinical data comparing a proposed biosimilar product with a non-U.S.-licensed comparator product be used to support a demonstration of biosimilarity to a U.S.-licensed reference product? What type of bridging data or information would be needed to scientifically justify the relevance of the comparative data?

E. Definition of a Biological Product

The BPCI Act changes the statutory authority under which certain protein products will be regulated by amending the definition of "biological product" in section 351(i) of the PHS Act to include a protein (except any chemically synthesized polypeptide) before the phrase "or analogous product." In light of the absence of scientific consensus on the distinction between the categories of "protein" and "polypeptide" or "peptide," FDA may establish a regulatory definition of "protein" and "any chemically synthesized polypeptide" to clarify the authority under which such products will be licensed and regulated and, to the extent possible, avoid the conflicting regulation of certain products (*i.e.,* those that are manufactured through either synthetic and recombinant technology) under different authorities.

FDA seeks comments on the following issues:

1. What scientific and technical factors should FDA consider if it develops a regulatory definition for the category of "protein" (as distinguished from peptide or polypeptide)?

2. What scientific and technical factors should FDA consider if it develops a regulatory definition for the category of "any chemically synthesized polypeptide"?

F. Guidances

Although the issuance or nonissuance of guidance does not preclude submission or agency review of, or action on, a 351(k) application, we are interested in obtaining public input regarding priorities for issuing guidance documents for industry (*see* section 351(k)(8) of the PHS Act).

FDA seeks comments on the following issues:

1. What types of guidance documents for industry should be a priority for the agency during the early period of implementation?

2. Section 351(k)(8)(E) of the PHS Act permits the agency to indicate in a guidance document that the science and experience, as of the date of the guidance document, with respect to a product or product class (not including any recombinant protein) does not allow approval of a 351(k) application for such a product or product class. What scientific and technical factors should the agency consider in determining if the existing science and experience are sufficient to allow approval for a product or product class under section 351(k) of the PHS Act?

G. Exclusivity

The BPCI Act provides for a 12-year period of marketing exclusivity from the date of first licensure of the reference biological product, during which approval of a 351(k) application cannot be made effective (*see* section 351(k)(7) of the PHS Act). The date of first licensure does not apply to a license for or approval of:

- A supplement for the biological product that is the reference product; or
- A subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
- A subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a related entity) for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency (*see* section 351(k)(7)(C) of the PHS Act).

FDA seeks comments on the following issues:

1. In light of the potential transfer of BLAs from one corporate entity to another and the complexities of corporate and business relationships, what factors should the agency consider in determining the types of related entities that may be ineligible for a period of 12-year exclusivity for a subsequent BLA?

2. What factors should the agency consider in determining whether a modification to the structure of the licensed reference biological product results in a change in safety, purity, or potency, such that a subsequent BLA may be eligible for a second 12-year period of marketing exclusivity?

H. Transition Provisions

The BPCI Act requires that an application for a biological product, which now includes the category of "protein (except any chemically synthesized polypeptide)," must be submitted under section 351 of the PHS Act, rather than under section 505 of the FD&C Act. However, the BPCI Act provides an exception for certain biological products that are in a "product class" for which an application has been approved under section 505 of the FD&C Act prior to March 23, 2010. An application for a biological product in these product classes may be submitted under section 505 of the FD&C Act until March 23, 2020, unless there is another biological product licensed under section 351(a) of the PHS Act that could serve as the reference product for the application, if the application were submitted under section 351(k) of the PHS Act (see section 7002(e) of the BPCI Act).

FDA seeks comments on the following issues:

1. What scientific factors should FDA consider in defining and applying "product class" for purposes of determining which applications for biological products may be submitted under the FD&C Act during the 10-year transition period?

2. What scientific factors should FDA consider in determining whether another biological product approved under section 351(a) of the PHS Act could serve as the reference product for an application submitted under section 351(k) of the PHS Act?

I. User Fees

The BPCI Act amends section 735 of the FD&C Act (21 U.S.C. 379g) to include 351(k) applications in the definition of a "human drug application" for the purposes of the prescription drug user fee provisions (*see* section 7002(f)(3) of the BPCI Act). The BPCI Act requires FDA to develop recommendations to present to Congress by January 15, 2012, for goals for the process of reviewing 351(k) applications, and plans for meeting those goals, for the first five fiscal years after FY 2012 (see section 7002(f)(3) of the BPCI Act).

FDA seeks comments on the following issues:

1. If the existing fee structure under the Prescription Drug User Fee Act (PDUFA) were to be considered as a model in establishing a user fee structure for applications and supplements for proposed biosimilar and interchangeable biological products, what factors and changes should FDA take into consideration, and why?

2. What factors should FDA take into account when considering whether to recommend that user fees for biosimilar and interchangeable biological products should also be used to monitor safety after approval?

In addition, FDA seeks to identify potential participants in any negotiations of user fee programs for biosimilar and interchangeable biological products, specifically companies that would be affected by such a user fee program and industry associations representing such companies. FDA requests that commenters identify these potential participants by sending to *Biosimilars UserFeeProgram@fda.hhs.gov* the following information regarding any company that may be subject to a user fee program for biosimilar and interchangeable biological products, or any industry association representing such companies: The name of the entity; contact person; e-mail address; and a phone number.

III. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-served basis. Individuals who wish to present at the public hearing must register by sending an e-mail to *biosimilarspublicmtg@fda.hhs.gov* on or before October 11, 2010, and provide complete contact information, including name, title, affiliation, address, e-mail, and phone number. Those without e-mail access may register by contacting Sandra Benton (*see* **FOR FURTHER INFORMATION CONTACT**). FDA has included questions for comment in section II of this document. You should identify the section and the number of each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available an agenda at *http://www.fda.gov/Drugs/NewsEvents/ucm221688.htm* approximately 2 weeks prior to the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit to FDA an electronic copy of their presentation to *biosimilarspublicmtg@fda.hhs.gov* on or before October 27, 2010.

If you need special accommodations because of disability, please contact Sandra Benton, (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live Webcast of this public hearing will be viewable at the following Web addresses on the days of the public hearing: *http://www.fda.gov/Drugs/NewsEvents/ucm221688.htm.* A video record of the public hearing will be available at the same Web addresses for one year.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic or written comments to the Division of Dockets Management (*see* **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

VI. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (*see* **ADDRESSES**) and on the Internet at http://www.regulations.gov approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Room 6–30, Rockville, MD 20857.

Dated: September 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24853 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0496]

Cooperative Agreement To Support Capacity Building Activities Through the World Health Organization Global Foodborne Infections Network

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application to award a cooperative agreement to the World Health Organization (WHO) Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and in support of the WHO Global Foodborne Infections Network (GFN) and to provide guidance to the WHO on a framework for the development of an international network to promote and enhance collaboration on harmonization and data sharing among countries with Antimicrobial Resistance (AMR) surveillance programs.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Program Contact: Patrick McDermott, Division of Animal and Food Microbiology, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Mod II, rm. 1505, Rockville, MD 20855, 301–210–4213, FAX: 301–210–4685, email: *Patrick.McDermott@fda.hhs.gov*.

Management Contact: Katherine C. Bond, Office of International Programs, Office of the Commissioner, FDA, White Oak Bldg. 32, rm. 3300, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8318, FAX: 301–595–5058, email: *Katherine.Bond@fda.hhs.gov*.

Grants Contact: Kimberly Pendleton, Division of Acquisition and Grants, FDA, 5630 Fishers Lane (HFA–500), rm. 2104, Rockville, MD 20857, 301–827–9363, FAX: 301–827–7101, email: *kimberly.pendleton@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please contact Kimberly Pendleton.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

[RFA–FD–10–006]

[Catalog of Federal Domestic Assistance Number(s): 93.103 *https://www.cfda.gov*]

A. Background

The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for a cooperative agreement to the WHO GFN. This project represents a collaborative agreement between the WHO and FDA aimed at capacity building in laboratory based surveillance of foodborne pathogens and disease in developing regions to support AGISAR and GFN to enable FDA to realize its goal of developing an international database for human and animal isolates of foodborne pathogens and their susceptibility profiles.

B. Research Objectives

- Support WHO capacity building activities with member countries for AMR monitoring (development of AMR training modules for GFN training courses, and hosting of visiting scientist from developing countries).
- Develop harmonized schemes for monitoring antimicrobial resistance in zoonotic and enteric bacteria to include appropriate sampling.
- Promote information sharing on AMR (development of a global AMR databank).
- Provide expert advice to WHO, and promote WHO and FDA collaborative work to advise WHO Member States on containment of AMR with a particular focus to Human Critically Important Antimicrobials. AGISAR should be the core advisory group to review criteria for ranking human and animal antimicrobials to be reviewed by WHO; and FDA's resources could be used in support of AGISAR's participation.
- Support and advise WHO on selection of sentinel sites to be strategically identified around the globe and designing pilot projects to conduct integrated surveillance of antimicrobial resistance.
- Promote development of standardized methods for monitoring antimicrobial use and work with member states for the implementation of these methods at the country-level.
- Promote the development of published articles on the emergence of AMR threats and challenges, and the