Congressional Record).[1] This draft guidance addresses one of these goals with the creation of a guidance document that addresses enriched trial designs. The guidance defines and discusses three enrichment strategies: Decreasing heterogeneity, predictive enrichment, and prognostic enrichment. The guidance also discusses general clinical trial design considerations, provides examples of potential clinical trial designs, and discusses regulatory considerations when using enrichment strategies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on clinical trial designs employing enrichment strategies to support approval of human drugs and biological products. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. Electronic Access

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

Dated: November 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30274 Filed 12–14–12; 8:45 am]

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[1] See ''Section A: PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 Through 2012'' (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1002]

Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Food Facility Registration (Fifth Edition).'' The guidance provides updated information pertaining to registration of human and animal food facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA) on January 4, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Amy Barringer, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Food Facility Registration (Fifth Edition),'' which replaces the fourth edition of a guidance entitled ''Questions and Answers Regarding Registration of Food Facilities (Edition 4)'' issued in August 2004. The guidance provides updated information pertaining to the registration of food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

On October 10, 2003, FDA issued an interim final rule (68 FR 58894) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415.

Section 102 of FSMA (Pub. L. 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act, in relevant part, to require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA. This revised edition of the guidance includes new information relating to the FSMA amendments to section 415.

The first edition of this document was issued as level 2 guidance under § 10.115 (21 CFR 10.115) and was made available on FDA's Web site on December 4, 2003. The second, third, and fourth editions of this document were issued as level 1 guidance documents under § 10.115 and were made available on FDA's Web site on January 12, 2004, February 17, 2004, and August 2004, respectively. This revision (fifth edition) is being issued as a level 1 guidance and includes questions and answers relating to the FSMA amendments to section 415 of the FD&C Act. In addition, the guidance provides non-substantive revisions to clarify, delete, and renumber the questions and answers in edition 4.

This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 as a level 1 guidance. The Agency will accept comments at any time, but it is implementing this guidance immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate.

The guidance represents the Agency's current thinking on food facility registration. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB control number 0910–0502.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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 guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30328 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1167]

Ag-Mark, Incorporated, et al.; Proposal To Withdraw Approval of New Animal Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity to request a hearing on the Agency's proposal to withdraw approval of 19 new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required periodic reports for these applications.

DATES: Submit written requests for a hearing by January 16, 2013; submit data and information in support of the hearing request by February 15, 2013.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. FDA–2012–N–1167 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9238, email: *vernon.toelle@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new animal drugs are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 514.80 (21 CFR 514.80). The holders of the approved applications listed in table 1 of this document have failed to submit the required annual reports and have not responded to the Agency's repeated requests for submission of the reports including, in all cases, a request by certified mail.

TABLE 1—APPROVED NADAS AND ANADAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN MADE

NADA/ANADA No.	Trade name (drug)	Sponsor	Citation in 21 CFR
009–252	FUMIDIL B (bicyclohexylammonium fumagillin)	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.	520.182
034–601	SYNCHRO–MATE (flurogestone acetate)	G. D. Searle LLC, 4901 Searle Pkwy., Skokie, IL 60077.	529.1003
039–284	Swisher Super Broiler 300–108 (amprolium, ethopabate, bacitracin zinc, and roxarsone).	Swisher Feed Division, William Davies Co., Inc., P.O. Box 578, Danville, IL 61832.	558.58
040–920	Chick Grower-Developer Fortified (amprolium)	Honeggers and Co., Inc., 201 W. Locust St., Fairbury, IL 61739.	Not codified
094–223	Canine Worm Caps (n-butyl chloride)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.	520.260
098–429	Medic-Meal-T Premix (tylosin phosphate)	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.	558.625
098–639	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435.	558.630
106–507	TYLAN 10 (tylosin phosphate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.	558.625
110–044	PRO–TONE Plus Pak GF T–1 (tylosin phosphate)	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.	558.625
117–688	Dichlorophene & Toluene Capsules	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.	520.580
120–614	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363	558.630
120–671	Pet-Worm-Caps (dichlorophene and toluene)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.	520.580
121–147	Nutra-Mix TYLAN (tylosin phosphate)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	558.625
122–522	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.	558.630