

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Parent of Youth Baseline Survey Participants/ Parent Baseline Questionnaire.	10,026	1	10,026	0.17 (10 minutes)	1,704
United States Youth aged 13 to 17/First Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/First Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
United States Youth aged 13 to 17/Second Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/Second Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
United States Youth aged 13 to 17/Third Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/Third Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
Total Hours	37,836

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

Dated: September 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0928]

Draft Guidance for Industry on Recommendations for Preparation and Submission of Animal Food Additive Petitions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #221) entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions.”

This draft guidance describes the types of information that FDA’s Center for Veterinary Medicine (CVM) recommends for inclusion in food additive petitions (FAPs) submitted for food additives intended for use in food for animals. It is intended to help the petitioner submit such FAP information in a consistent and appropriate manner.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments

on the draft guidance by November 12, 2013.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6864, sharon.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #221) entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions.” It is intended to help petitioners submit FAP information in a consistent and appropriate manner.

The requirements for submitting an animal food additive petition to FDA are set forth in section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) and 21 CFR part 571. This draft guidance provides information for complying with these requirements.

This draft guidance includes the following information:

- How to determine if an animal food ingredient is already the subject of an approved FAP.
- Who to contact for more information about approved food additives.
- Who to contact for more information on how to submit an FAP for approval.
- When and how to request a pre-petition consultation with CVM before submitting an FAP.
- When and how to submit study designs for CVM review.
- What data CVM considers adequate to support an FAP.
- Where to find other FDA guidances that may be helpful when preparing and submitting an FAP to CVM.
- General recommendations for the format of an FAP submission.
- Where and how to submit an FAP.

II. Significance of Guidance

This level 1 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 §§ 571.1 and 571.6 have been approved under 0910–0546.

IV. 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>.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: September 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Society of Clinical Research Associates—Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SoCRA).” The public workshop regarding FDA’s clinical trial requirements is designed to aid the clinical research professional’s understanding of the mission, responsibilities, and authority of FDA, and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs).

Individual FDA representatives will discuss the informed consent process including the informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRBs, and of research sponsors.

Date and Time: The public workshop will be held on November 6 and 7, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the JW Marriott Atlanta Buckhead Hotel, 3300 Lenox Rd. NE., Atlanta, GA 30326, 404–262–3344.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$185.00 plus applicable taxes (available until October 15, 2013, or until the SoCRA room block is filled).

Contact Person: JoAnn Pittman, Food and Drug Administration, 60 Eighth Street NE., Atlanta, GA 30309, voicemail: 404–253–1272, FAX: 404–253–1202, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: SoCRAMail@aol.com, Web site: www.socra.org.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows:

SoCRA member	\$575.00.
SoCRA nonmember (includes membership).	\$650.00.
Federal Government SoCRA member.	\$450.00.
Federal Government SoCRA non-member.	\$525.00.
FDA Employee	(Free) Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: SoCRAMail@aol.com at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category

1 Credit(s)TM. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to “SoCRA”. Mail to: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914.

To register via the Internet, go to: http://www.socra.org/html/FDA_Conference.htm. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: SoCRAMail@aol.com.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA’s Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA’s Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working