TABLE 3—STUDY 2 DESIGN: HEMATOLOGY

Indication presentation			
Material information in superimposed text only	Material information in audio only	Material information in superimposed text + audio	Material information not in superimposed text or audio (Control)
Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.

Note. Study 2 will use the overall survival ad from Study 1.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interview screener	30	1	30	0.08 (5 minutes)	2.4
Cognitive Interviews	18	1	18	1 (60 minutes)	18
Pretests 1 and 2 screener	200	1	200	0.08 (5 minutes)	16
Pretests 1 and 2	120	1	120	0.33 (20 minutes)	39.6
Study 1 screener	1,167	1	1,167	0.08 (5 minutes)	93.36
Study 1	700	1	700	0.33 (20 minutes)	231
Study 2 screener	867	1	867	0.08 (5 minutes)	69.36
Study 2	520	1	520	0.33 (20 minutes)	171.6
Total					641.32

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

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Kim, J., J. Gao, L. Amiri-Kordestani, et al., ''Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer.'' The Oncologist, 10.1634/theoncologist.2018-0761, 2019. Available from: *http://theoncologist.alphamedpress.org/content/early/2019/05/16/theoncologist.2018-0761.short?rss=1*.
2. Aikin, K.J., A.C. O'Donoghue, C.M. Squire, et al., ''An Empirical Examination of the FDAAA-Mandated Toll-Free Statement for Consumer Reporting of Side Effects in Direct-to-Consumer Television Advertisements.'' *Journal of Public Policy & Marketing,* 35(1):108–123, 2016.
3. Sullivan, H.W., V. Boudewyns, A.C. O'Donoghue, et al., ''Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study.'' *Journal of Public Policy & Marketing,* 36(2):236–245, 2017.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13128 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 22, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Generally Recognized as Safe (GRAS): Notification Procedure—21 CFR Part 170, Subpart E and 21 CFR Part 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 349) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in (part 170) 21 CFR part 170 and (part 570) 21 CFR part 570 for human food and animal food, respectively. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed.

In the **Federal Register** of March 12, 2019 (84 FR 8876), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	25	1	25	170	4,250
Total			75		21,250

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

Our estimated burden reflects an overall increase of 8,500 hours, which corresponds to an increase in GRAS submissions for human food from 50 to 100 we have received over the last 2 years.

Dated: June 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13220 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Small Rural Hospital Transition Project (SRHT), OMB No. 0906–0026—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 20, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the