DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Trafficking Victims Tracking System.

OMB No.: 0970—NEW.

Description: The Trafficking Victims Protection Act, Public Law 106–386, Division A, 114 Stat. 1464 (2000), requires the Department of Health and Human Services (HHS) to certify adult alien (''foreign'') victims of severe forms of trafficking in persons (''human trafficking'') who are willing to assist law enforcement in the investigation and prosecution of human trafficking, unless unable to cooperate due to physical or psychological trauma, and who have either made a bona fide application for T nonimmigrant status that has not been denied or been granted Continued Presence (CP) from the U.S. Department of Homeland Security (DHS). Issued by the Office of Refugee Resettlement (ORR) within the HHS Administration for Children and Families, certification letters grant adult foreign victims of human trafficking access to federal and state benefits and services to the same extent as refugees.

In general, ORR initiates the certification process when it receives a notice from DHS that DHS has granted a foreign victim of trafficking CP or T nonimmigrant status, or has determined an application for T nonimmigrant status is bona fide. To issue certification letters, it is necessary for ORR to collect information from a victim's representative, such as an attorney, case manager, or law enforcement victim specialist, including an address to send the letter. In line with other ORR Anti-Trafficking in Persons Program activities, ORR may ask if the victim is in need of a service provider and the current location (city, state) of the victim, and refer the victim to an appropriate service provider in his or her area, if requested. ORR will also ask about the victim's language and urgent concerns, such as medical care or housing, and transmit this information to the service provider.

Finally ORR collects information, such as the victim's sex and the type of human trafficking the victim experienced, to provide to Congress in an annual report on U.S. Government activities to combat trafficking that is prepared by the U.S. Department of Justice. Congress requires HHS and other appropriate Federal agencies to report, at a minimum, information on the number of persons who received benefits or other services under subsections (b) and (f) of section 7105 of Title 22 of the U.S. Code, the TVPA, in connection with programs or activities funded or administered by HHS. HHS includes in these annual reports additional information about the victims that it collects when assisting each victim to obtain certification or eligibility. ORR will store this information and any other details regarding the victim's case in the Trafficking Victims Tracking System (TVTS) on ORR's secure database. Other details maintained in the victim's file may include ORR staff actions, referrals, and notes regarding the victim's interest in receiving services. Maintaining victim records on TVTS will ensure efficient service for victims, allow ORR staff to track victims' progress toward certification, verify their eligibility for benefits, and organize information for reporting to Congress.

The TVTS also includes information about foreign victims of trafficking and potential victims who were minors when an eligibility letter was sought from ORR. Information about these individuals is collected pursuant to an OMB-approved collection, OMB Control Number 0970–0362.

In January 2011, the Archivist of the United States approved an Electronic System Schedule for the disposition of TVTS records.

Respondents: Respondents can include attorneys, legal representatives, social service providers, case managers, and volunteers acting on behalf of the adult foreign victim of trafficking.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
	800	1	.1	80

Estimated Total Annual Burden Hours: 80.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–26723 Filed 11–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1794]

Agency Information Collection Activities; Proposed Collection; Comment Request; Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Ads

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, ''Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads.'' This project will examine the effects of variation in ad exposure frequency on perception and mental processing of risk and benefit information in direct-to-consumer (DTC) prescription drug ads.

DATES: Submit either electronic or written comments on the collection of information by January 12, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads—(OMB Control Number 0910—NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

In a typical promotional campaign, consumers may be exposed to a DTC prescription drug ad any number of times. Perceptual and cognitive effects of increased ad exposure frequency have been studied extensively using non-drug ads. For instance, one study demonstrated that a commercial message repeated twice generates better recall than a message broadcast only once (Ref. 1). Another study demonstrated that increased ad exposures improve product attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied (Ref. 2). Generally, it has been argued that first exposure to an ad results in attention, second exposure affects learning of the advertised message, and third and subsequent exposures reinforce the learning effects of the second exposure (Ref. 3). To our knowledge, the literature concerning ad exposure frequency has not been extended to include specific attention to prescription drug ads. Prescription drug ads are unique in that they are required to provide both benefit and risk information whereas other ad types tend to include only benefit information. The Office of Prescription Drug Promotion plans to examine the effects of variation in ad exposure frequency on perception and mental processing of risk and benefit information in DTC prescription drug ads through empirical research.

The main study will be preceded by up to two pretests designed to delineate the procedures and measures used in the main study. Across pretests and the main study, participants will be individuals who have been diagnosed with seasonal allergies. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Participants will be recruited in one of two geographic locations (Washington, DC and Raleigh-Durham, NC) for in-person administration of protocols.

The experimental design is summarized in Table 1. Participants will be randomly assigned to view a prescription drug ad one, three, or six times as part of clutter reels embedded in a 42 minute TV program. They will then answer preprogrammed survey questions on laptops. Preliminary measures are designed to assess perception, memory, judgments about the ad, intentions to use the medication advertised, and possible moderators of effects, such as need for cognition and demographics. The questionnaire is available upon request. Participation is estimated to take up to 2 hours.

TABLE 1—EXPERIMENTAL DESIGN

Experimental Arm No.	42 Minute television show, clutter reel No.					
	1	2	3	4	5	6
1 (views ad 1 time)	.....	.....	.....	.....	.....	Mock DTC ad.
2 (views ad 3 times)	Mock DTC ad	.....	.....	Mock DTC ad	.....	Mock DTC ad.
3 (views ad 6 times)	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in the following table, we will have sufficient power to detect small-to-medium sized effects in the main study.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Pretest 1 screener completes (assumes 10% eligible)	4,150	1	4,150	0.08 (5 minutes)	332
Pretest 2 screener completes (assumes 10% eligible)	4,150	1	4,150	0.08 (5 minutes)	332
Number of main study screener completes (assumes 10% eligible).	620	1	620	0.08 (5 minutes)	50
Pretest 1 completes	420	1	420	2	840
Pretest 2 completes	420	1	420	2	840
Number of completes, main study	620	1	620	2	1240
Total					3,634

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

References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Singh, S. N., D. Linville, and A. Sukhdial, ''Enhancing the Efficacy of Split Thirty-Second Television Commercials: An Encoding Variability Application,'' *Journal of Advertising,* 24, pp. 13–23 (1995).
2. Haugtvedt, C. P., et al., ''Advertising Repetition and Variation Strategies: Implications for Understanding Attitude Strength,'' *Journal of Consumer Research,* 21, pp. 176–189 (1994).
3. Naples, M. J., ''Effective Frequency: Then and Now,'' *Journal of Advertising Research,* 37, pp. 7–12 (1997).

Dated: November 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26698 Filed 11–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–F–1539]

DSM Nutritional Products; Food Additive Petition (Animal Use); Ethoxyquin; Environmental Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an environmental assessment filed by DSM Nutritional Products in support of their petition proposing that the food additive regulations be amended to provide for the safe use of ethoxyquin in vitamin D formulations, including 25-hydroxyvitamin D_3, used in animal food.

ADDRESSES: 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, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 2013 (78 FR 77384) FDA published notice that a food additive petition (FAP) had been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition (FAP 2276) proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of ethoxyquin as a chemical preservative in vitamin D formulations, including 25-hydroxyvitamin D_3, used in animal food. In that document, FDA noted that the petitioner had requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(k).

Upon further review and request by FDA, the petitioner has filed an environmental assessment. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the Agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: November 6, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–26709 Filed 11–10–14; 8:45 am]

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