Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications; OMB Control Number 0910–0810—Extension

In order to conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will create and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these health communication messages have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and studies relating to the control and prevention of disease. In conducting such research, FDA will employ formative pretests. Formative pretests are conducted on a small scale, and their focus is on developing and assessing the likely effectiveness of communications with specific target audiences. This type of research involves: (1) Assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs and (2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions.

Formative pretesting is a staple of best practices in communications research. Obtaining voluntary feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about the perceived effectiveness of messages, advertisements, and materials in reaching and successfully communicating with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials, including questionnaires or images, directed at consumers while the materials are still in the developmental stage.

In the **Federal Register** of February 13, 2018 (83 FR 6190), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA-related comment was received.

Comment: The comment recommends that FDA should research and develop communications about educating adults about the continuum of risk, and educating adults to not provide tobacco products to youth.

Response: FDA appreciates the comment. The content and focus on studies submitted through this generic clearance will depend on Agency priorities and needs, and is not yet determined at this time.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	130,500	1	130,500	0.083 (5 minutes)	10,831
Self-Administered Surveys	27,000	1	27,000	0.33 (20 minutes)	8,910
Total					19,741

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

The number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. The burden for this information collection extension is proposed to increase by 12,613 hours since the last OMB approval. The burden increase is due to an increase in the number of respondents and the categories of respondents.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17044 Filed 8–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2495]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the guidance to assist manufacturers who wish to voluntarily label their foods (human and animal) as being made with or without bioengineering, or the use of bioengineered ingredients, to ensure that labeling is truthful and not misleading.

DATES: Submit either electronic or written comments on the collection of information by October 9, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 9, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 9, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–2495 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: 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, including each proposed extension of an existing 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.

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

OMB Control Number 0910–0807—Extension

This information collection supports Agency guidance. Section 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343) generally governs the labeling of foods. Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or

under such conditions of use as are customary or usual.

In the **Federal Register** of May 29, 1992 (57 FR 22984), we published a ''Statement of Policy: Foods Derived from New Plant Varieties'' (the 1992 Policy). The 1992 Policy applies to foods for humans and animals that are developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology, which is often referred to as ''rDNA technology,'' ''genetic engineering,'' ''biotechnology,'' or ''bioengineering,'' and more recently as ''modern biotechnology.'' The 1992 Policy provides guidance to industry on scientific and regulatory issues related to bioengineered foods and solicited written comments from interested persons. It includes guidance on questions to be answered by developers of foods from new plant varieties to ensure that the new products are safe and comply with applicable legal requirements.

The 1992 Policy stated that the method of development of a new plant variety, including plants developed using bioengineering, is not information that is material under section 201(n) of the FD&C Act and, therefore, would not be required in the labeling of food. This conclusion is consistent with our historic interpretation of section 201(n) of the FD&C Act, in that the method of plant breeding is not required to be disclosed in labeling. In the 1992 Policy, we addressed, among other things, the labeling of foods derived from new plant varieties, including plants developed by bioengineering. In the 1992 Policy, we explained that we were not establishing special labeling requirements for foods from bioengineered plants as a class of foods because we did not find any basis for concluding that foods from bioengineered plants, as a class, differ from other foods in any meaningful or uniform way, or that foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

The guidance entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants'' is intended to assist manufacturers that wish to voluntarily label their foods (human or animal) as being made with or without genetic engineering or the use of genetically engineered ingredients, to ensure that such labeling is truthful and not misleading. The guidance is available at *https://www.fda.gov/FoodGuidances.* The information that the manufacturers will collect is documentation of handling practices so that they can truthfully label their products to indicate, if they so choose, whether the food has or has not been developed using genetic engineering.

In general, we anticipate that manufacturers that claim that a product is not developed using bioengineered material would substantiate the claim. We suggest that manufacturers document practices and procedures to substantiate a claim that a food was not developed using genetic engineering. Examples of documentation that we anticipate will demonstrate practices and procedures are recordkeeping, and certifications or affidavits from farmers, processors, and others in the food production and distribution chain. We are neither suggesting that firms maintain a certain set list of documents nor are we suggesting that anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's judgment to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: The respondents to the proposed collection of information are manufacturers of foods that were or were not derived from genetically engineered plants who wish to voluntarily label their food products.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping per the Guidance	85	4	340	1	340

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

The number of recordkeepers and respondents reflects the number of food products that are labeled using the terms ''biotechnology'' and ''GMO'' (genetically modified organism). We estimate a recordkeeping burden to retain paperwork to substantiate that the food or ingredient is produced without genetic engineering only for products that are not also already labeled using the term ''organic.'' We did not include products that are labeled ''organic'' in the estimated annual recordkeeping burden because, according to a final rule in the **Federal Register** of December 21, 2000 (65 FR 80548) issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as ''organic'' would not be permitted to contain genetically engineered materials. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using genetic engineering for these certified organic products.

We based our estimates of the recordkeeping burden (table 1 of this document) on data from Labelbase by FoodEssentials. Labelbase is a custom online system for accessing consumer-packaged goods product data; the database contains more than 250,000 product labels that can be searched by keyword, ingredient, nutrient, allergen, label claim, or food additive, for example. Using this database, we have identified 540 food manufacturers who produce 2,160 products with the term ''bioengineered'' or ''GMO'' on their labels; this estimate includes manufacturers of human food and pet food. In addition, the National Center for Appropriate Technology's National Sustainable Agriculture Information Center maintains on its website a list of Organic Livestock Feed Suppliers. Using this list, we have identified 54 livestock feed suppliers that would be likely to include a statement about bioengineering on the label of their products and thus would have documentation to substantiate their claim.

Of the 2,160 human food and pet food products that we have identified as using the term ''bioengineered'' or ''GMO'' on their labels (presumably used in a context to designate foods that are not bioengineered), 1,140 of these products (285 manufacturers) also use the term ''organic'' on the label; 1,020 products do not use the term ''organic''

on the label (2,160 − 1,140 = 1,020 products not organics; 540 − 285 = 255 manufacturers of not organic products). In addition, the 54 livestock feed suppliers are also organic producers, thus the 216 products attributed to these manufacturers already are considered to be labeled ''organic.'' Thus, there are 1,020 products made by 255 human food and pet food manufacturers that would need to substantiate that their product or ingredient was not genetically engineered.

We estimate that the burden of maintaining the documentation is a one-time burden; the document to substantiate that the product or ingredient was produced without genetic engineering only needs to be generated once and then kept on file. To annualize this one-time burden, we divide by 3 because paperwork burden collections are approved on a 3-year cycle (255/3 = 85). Thus, we estimate in table 1 that, on average, 85 manufacturers annually will collect and keep information that substantiates their label claim for four products (1,020 products/3 = 340 products/85 manufacturers = 4 products per manufacturer).

We estimate this one-time recordkeeping burden to be 1 hour per product that makes use of a labeling claim, which results in a burden of 1 hour for a total annualized recordkeeping burden of 340 hours (85 manufacturers × 4 records per manufacturer × 1 hour per record).

We do not estimate any reporting burden or third-party disclosure burden associated with this information collection. Manufacturers who want to make use of this voluntary labeling claim option are considered to be those that already have such wording on their products' labels. We do not expect that this guidance will cause labels already in the marketplace to need to be reworded.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17024 Filed 8–8–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–0998]

Determination That PROLIXIN (Fluphenazine Hydrochloride) Tablets, 1 Milligram, 2.5 Milligrams, 5 Milligrams, and 10 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PROLIXIN (fluphenazine hydrochloride) tablets, 1 milligram (mg), 2.5 mg, 5 mg, and 10 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for fluphenazine hydrochloride tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, is the subject of NDA 011751, held by Apothecon Pharmaceuticals, a Bristol-Myers Squibb Company, and initially approved on March 15, 1967. PROLIXIN is indicated in the management of manifestations of psychotic disorders.

In a letter dated October 5, 2006, Bristol-Myers Squibb Company requested withdrawal of NDA 011751 for PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of NDA 011751, effective March 13, 2009.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated March 5, 2018 (Docket No. FDA–2018–P–0998), under 21 CFR 10.30, requesting that the Agency determine whether PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was