ability to correct misinformation is related to (a) corrective ad similarity to the original ad and (b) time delay between original ad and corrective ad exposure.

We will vary these two characteristics to create a study with a 4x3 experimental design (see table 2).

TABLE 2—DESIGN OF PHASE 2: AD SIMILARITY BY EXPOSURE DELAY

Corrective ad similarity	Exposure delay		
	None	1 Week	1 Month
Same ad elements			
Some similar elements			
Different ad elements			
Control (Do not see corrective)			

Prior to conducting the main study, we will pretest the stimuli, questionnaires, and data collection process. The first set of pretests will focus on the stimuli, and its purpose will be to (a) ensure the stimuli display properly, (b) ensure participants perceive the stimuli as realistic, and (c) ensure participants notice the original and corrective messages in the ads. The second pretest will focus on the questionnaires and data collection process. Its purpose will be to (a) ensure that survey questions solicit responses that meet the study's analytic goals and (b) ensure data are captured and stored accurately for each question.

FDA estimates the burden of this collection of information as follows: 30 minutes in the pretests and each phase of the study, for a burden of 3,092 hours. This will be a one time (rather than annual) collection of information. The questionnaire is available upon request.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretests	1,250	1	1,250	0.5 (30 minutes)	625
Phase 1 Screener	3,228	1	3,228	0.033 (2 minutes)	108
Phase 1	1,000	1	1,000	0.5 (30 minutes)	500
Phase 2 Screener	10,768	1	10,768	0.033 (2 minutes)	359
Phase 2	3,000	1	3,000	0.5 (30 minutes)	1,500
Total	19,246				3,092

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

IV. 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.

1. Darke, P.R., L. Ashworth, and R.J.B. Ritchie, ''Damage From Corrective Advertising: Causes and Cures,'' *Journal of Marketing,* vol. 72, pp. 81–97, 2008.

2. Mazis, M.B. and J.E. Adkinson, ''An Experimental Evaluation of a Proposed Corrective Advertising Remedy,'' *Journal of Marketing Research,* vol. 13, pp. 178–183, 1976.

3. Mazis, M.B., D.L. McNeill, and K.L. Bernhardt, ''Day-After Recall of Listerine Corrective Commercials,'' *Journal of Public Policy & Marketing,* vol. 2, pp. 29–37, 1983.

4. Singer, N., *A Birth Control Pill That Promised Too Much,* New York Times, February 11, 2009, p. B1.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4777 Filed 2–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0797]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

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 March 30, 2012.

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 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes States to

enforce certain sections of the FD&C Act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the FD&C Act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of November 9, 2011 (76 FR 69742), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

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

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the Agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4776 Filed 2–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0558]

Determination That PHENURONE (Phenacemide) Tablet, 500 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) has determined that PHENURONE (phenacemide) Tablet, 500 milligrams (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 phenacemide tablet, 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6234, Silver Spring, MD 20993–0002, 301–796–3602.

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 approved 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 a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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.

PHENURONE (phenacemide) Tablet, 500 mg, is the subject of NDA 007707, held by Abbott Laboratories, and initially approved on June 28, 1951. PHENURONE is an oral anticonvulsant indicated for the treatment of epilepsy.

In a letter dated May 14, 2003, Abbott Laboratories requested withdrawal of NDA 007707 for PHENURONE (phenacemide) Tablet. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 007707, effective June 4, 2004.

Schiff & Company submitted a citizen petition dated October 16, 2008 (Docket No. FDA–2008–P–0558), under 21 CFR 10.30, requesting that the Agency determine whether PHENURONE (phenacemide) Tablet, 500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that PHENURONE (phenacemide) Tablet, 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PHENURONE (phenacemide) tablet, 500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of