

**DATES:** Fax written comments on the collection of information by April 25, 2013.

**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 0910-0331. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5733, *domini.bean@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.

**Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93 (OMB Control Number 0910-0331)—Extension**

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) requires that FDA be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6). Section 403(r)(6) of the FD&C Act requires that FDA be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and

accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The procedural regulation for this program is codified at 21 CFR 101.93. Section 101.93 provides submission procedures and identifies the information that must be included in order to meet the requirements of section 403 of the FD&C Act.

*Description of Respondents:* Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the **Federal Register** of January 18, 2013 (78 FR 4153), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice. One comment in the letter suggested that electronic submission could potentially decrease the reporting burden. FDA agrees and is in the process of developing a method of receiving submissions electronically.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93	2,200	1	2,200	0.75	1,650

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

We believe that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the FD&C Act in submitting information regarding section 403(r)(6) statements on labels or in labeling of dietary supplements. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403 of the FD&C Act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a submission, for a total of 1,650 hours (2,200 × 0.75). This estimate is based on the average number of notification submissions received by us in the preceding 3 years.

Dated: March 20, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2013-06823 Filed 3-25-13; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-P-0649]

**Determination That QUESTRAN (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, and QUESTRAN LIGHT (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, Were 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 QUESTRAN (cholestyramine for oral suspension, USP), equivalent to (EQ) 4 grams (g), and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug applications (ANDAs) that refer to these drugs, and it will allow FDA to approve ANDAs that refer to these drugs as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, 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 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.

QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 16-640, held by Bristol-Myers Squibb, and initially approved on August 3, 1973. QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 19-669, also held by Bristol-Myers Squibb, and initially approved on December 5, 1988. QUESTRAN and QUESTRAN LIGHT are indicated as adjunctive therapy for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoprotein cholesterol) who do not respond adequately to diet.

In a letter dated May 31, 2012, Bristol-Myers Squibb notified FDA that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were

being discontinued, and FDA moved the drug products to the “Discontinued Drug Product List” section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated June 19, 2012 (Docket No. FDA-2012-P-0649), under 21 CFR 10.30, requesting that the Agency determine whether QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address QUESTRAN LIGHT, that version of the drug product has also been discontinued. On our own initiative, we have also determined whether QUESTRAN LIGHT was withdrawn for safety or effectiveness reasons.

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 QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, 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 either product was withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to QUESTRAN or QUESTRAN LIGHT. Additional ANDAs for cholestyramine and cholestyramine light for oral suspension, USP, EQ 4 g, may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that

labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 20, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0069; (Formerly FDA-2007D-0393)]

#### Guidance for Industry: Blood Establishment Computer System Validation in the User’s Facility; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Blood Establishment Computer System Validation in the User’s Facility” dated April 2013. The guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. The guidance announced in this document finalizes the draft guidance of the same title dated October 2007.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-