DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 24 2007
0639 7 NOV 29 A11:28

Mr. Anthony Celeste
Sr. Vice President
AAC Consulting Group/Kendle
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765

Re: Docket No. 2006P-0298/CP1

Dear Mr. Celeste:

This letter responds to your citizen petition dated July 25, 2006, requesting that the Food and Drug Administration (FDA) determine whether Eloxatin (oxaliplatin for injection), 50 and 100 milligrams (mg)/vial, sterile lyophilized powder for injection, was voluntarily withdrawn or withheld from sale for safety or efficacy reasons (Petition).

I. BACKGROUND

Oxaliplatin for injection is a chemotherapeutic agent indicated for adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. Eloxatin (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection (powder formulation), subject of new drug application (NDA) 21-492 held by Sanofi Aventis, was approved in August 2002. In January 2005, FDA approved Eloxatin (oxaliplatin injection), aqueous solution at a concentration of 5 mg/ milliliter (aqueous solution) (NDA 21-759), also held by Sanofi Aventis. Sanofi Aventis ceased manufacturing the Eloxatin powder formulation in June 2006.

II. DISCUSSION

A. Discontinuation of Powder Formulation from Marketing

You request that FDA determine whether Eloxatin (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection (NDA 21-492), held by Sanofi Aventis, was voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Eloxatin powder formulation was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will continue to list Eloxatin (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in the *Discontinued Drug Product List* of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book). This determination allows FDA to approve an abbreviated new drug application (ANDA) referencing Eloxatin powder formulation, as long as it meets the relevant legal and regulatory requirements for approval. See the

enclosed copy of the *Federal Register* notice announcing the FDA determination. Therefore, this request is granted.

B. Safety of a Generic Referencing the Discontinued Formulation

You request that FDA make a determination that a proposed generic product referring to the originally approved formulation (now discontinued) would not render the product less safe or effective than the currently marketed innovator's product (Petition at 1 and 3).

You state that the proposed generic would reference the discontinued powder formulation, not the currently marketed aqueous formulation, and describe the proposed generic product as identical to the referenced discontinued Eloxatin powder formulation (Petition at 2-3). As stated above, we have concluded that the discontinued product was not withdrawn for reasons of safety or effectiveness. If a proposed generic product meets the relevant statutory and regulatory requirements for approval, we would expect the generic drug product to be as safe and effective as the discontinued Eloxatin powder formulation.

Because the proposed generic would reference the discontinued powder formulation, and not the currently marketed aqueous solution, it is unnecessary to assess comparative safety and effectiveness between the two formulations. Therefore, this aspect of your request is denied.

C. Therapeutic Equivalence Between a Generic Referencing the Discontinued Formulation and the Currently Marketed Formulation

You request that FDA determine that the proposed generic product "would be therapeutically equivalent to the currently marketed product" (Petition at 3).

The Eloxatin powder formulation would be considered to be a different dosage form than the Eloxatin aqueous solution because injectable dry powders and injectable solutions are different dosage forms. Two drug products are rated as therapeutic equivalents in the Orange Book, only if, among other things, they are *pharmaceutical equivalents*, which is defined, in part, as being of the same dosage form (see page v of the preface of the Orange Book (27th Ed.)). An injectable dry powder would be considered a pharmaceutical alternative to an injectable solution, as described on page vi of the preface of the Orange Book (27th Ed.).

Therefore, your request to make a determination that the proposed generic is therapeutically equivalent to the currently marketed Eloxatin aqueous solution is denied.

III. CONCLUSION

We have concluded that the discontinued Eloxatin powder formulation was not withdrawn for reasons of safety or effectiveness and, therefore, FDA will accept ANDAs referencing this discontinued product. As a result, this aspect of your petition is granted.

For the above stated reasons, your requests to make a determination that the proposed generic would not be less safe and/or effective than, and would be therapeutically equivalent to, the currently marketed Eloxatin aqueous solution are denied.

Sincerely,

Janet Woodcock, M.D.
Acting Director
Center for Drug Evaluation and Research

Enclosure

Dated: November 16, 2007.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22920 Filed 11–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–08–06AY]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the Spanish-Language Campaign *"Good Morning Arthritis, Today You Will Not Defeat Us."*—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Arthritis affects nearly 43 million Americans, or about one in every five people, and is the leading cause of disability among adults in the United States. Limitations due to arthritis are particularly burdensome when they affect an individual's mobility, productivity, and ability to earn a living, as well as psychological and social well-being. Because of the broad public health impact of this disease, the Centers for Disease Control and Prevention (CDC) developed the National Arthritis Action Plan in 1998 as a comprehensive approach to reducing the burden of arthritis in the United States.

Hispanics are currently the fastest growing racial/ethnic group in the United States. Although Hispanic populations have a slightly lower prevalence rate of self-reported, doctor-diagnosed arthritis than the general population, Hispanics with arthritis report greater work limitations, and higher rates of severe pain than do Caucasian populations with arthritis. CDC has developed a Spanish-language campaign, *Good Morning Arthritis, Today you will not defeat us,* to deliver culturally appropriate public health messages about the benefits of physical activity as an arthritis management strategy. Campaign materials include print ads, 30 and 60 second radio ads and public service announcements, and desktop displays with brochures for pharmacies, doctors' offices, and community centers. The campaign is designed to reach Spanish speaking adults with arthritis who are aged 45–64, who have high school education or less, and whose annual income is less than $35,000. CDC plans to conduct the campaign in four experimental markets.

CDC requests clearance to conduct an evaluation of the campaign by collecting information from Spanish-speaking respondents in the four experimental markets and two control markets. An initial data collection will consist of telephone interviews, and will be based on a pre- and post-campaign evaluation design. A follow-up telephone interview, involving a subset of the initial respondents, will be conducted six months later. Results will be used to guide the public health practice of the 36 CDC-funded state arthritis programs and their partners.

There are no costs to respondents other than their time. The estimated annualized burden hours are 2,730.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Target Population of Hispanic Adults	Screener for Primary Pre- and Post Campaign Survey.	60,000	1	2/60
	Primary Pre- and Post Campaign Survey	2,400	1	13/60
	Screener for 6–Month Follow-up Survey	2,400	1	2/60
	6–Month Follow-up Survey	600	1	13/60

Dated: November 16, 2007.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22930 Filed 11–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006P–0291, 2006P–0299, 2006P–0298, 2006P–0309, and 2007P–0062]

Determination That ELOXATIN (Oxaliplatin for Injection), 50 and 100 Milligrams Per Vial, Sterile Lyophilized Powder for Injection, 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 ELOXATIN (oxaliplatin for injection), 50 and 100 milligrams (mg) per vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs 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 generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn 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).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, is the subject of approved NDA 21–492 held by Sanofi-Aventis. Oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, is a chemotherapeutic agent indicated for adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. Sanofi-Aventis ceased manufacturing ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in June 2006.

FDA received five citizen petitions, submitted under 21 CFR 10.30, requesting that the agency determine whether oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. The petitions were submitted as follows:

- Sicor Pharmaceuticals, Inc., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0291/CP1).
- Rothwell, Figg, Ernst & Manbeck, P.C., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0299/CP1).
- AAC Consulting Group submitted a citizen petition dated July 25, 2006 (Docket No. 2006P–0298/CP1).
- Frommer Lawrence & Haug LLP submitted a citizen petition dated August 4, 2006 (Docket No. 2006P–0309/CP1).
- Regulus Pharmaceutical Consulting, Inc., submitted a citizen petition dated February 20, 2007 (Docket No. 2007P–0062/CP1).

The agency has determined that ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant information has uncovered no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing agency records, FDA determines that for the reasons outlined previously, ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, 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. ANDAs that refer to ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that the labeling of this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: November 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22973 Filed 11–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Questionnaire Cognitive Interview and Pretesting (ARP/DCCPS/NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Questionnaire Cognitive Interview and Pretesting. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of the data collection is to conduct cognitive interviews, focus groups, Pilot household interviews, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common evaluation method is the cognitive interview, in which a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews. When possible, cognitive interviews are conducted in the survey's intended mode of administration. Cognitive interviewing provides useful information on questionnaire performance at minimal cost and respondent burden. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. There are no costs to respondents other than their time. The total estimated annualized burden hours are 600.