of the "high public interest value associated with parties fully complying with information requests concerning prescription drugs."

FDA Response: FDA is not aware of any request for a waiver under § 202.1(e)(6). If we receive such a waiver request in the future, we will consider this comment in determining whether or not to grant the request.

Concerning the statement that FDA has not received any advertisements requiring prior approval under § 202.1(j)(1) in the past 10 years, the comment said this may be indicative of FDA's failure to ensure compliance with this provision, rather than simply an indication that no advertisements are received under § 202.1(j)(1). The comment said that FDA should more vigorously investigate and penalize or otherwise sanction sponsors who fail to ensure that significant new adverse information about a drug that becomes known to the sponsors is advertised in compliance with § 202.1(j).

FDA Response: FDA properly enforces the requirements of § 202.1(j). Additionally, the Division of Drug Marketing, Advertising and Communication (DDMAC) works closely with the Office of New Drugs (OND) and sponsors to ensure that information about serious and significant risks that have not been widely publicized is appropriately presented in promotional labeling and advertising. FDA regularly communicates these requests to sponsors through supplement letters sent by OND review divisions and safety update letters sent by DDMAC. DDMAC is not aware of any drugs that have required prior approval under § 202.1(j)—but DDMAC is consistently in contact with OND and sponsors to ensure that promotional labeling accurately communicates serious and significant risk information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Type of submission	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
202.1(e)(6)	Waiver request to FDA	1	1	1	12	12
202.1(j)(1)	Submission of advertisement to FDA for prior approval.	1	1	1	2	2
202.1(j)(1)(iii)	Providing a program to FDA for assuring that adverse information about the drug will be publicized.	1	1	1	12	12
202.1(j)(4)	Voluntarily submitting the advertisement to FDA prior to publication for comment.	155	9	1,395	20	27,900
Total						27,926

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

TABLE 2—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

21 CFR section	Type of submission	Number of respondents	Annual frequency of disclosure	Total annual disclosure	Hours per disclosure	Total hours
202.1	Advertisements prepared in accordance with § 202.1.	355	47	16,685	400	6,674,000
202.1(j)(1)	Including information about the drug's fatalities or serious damage in the advertisement.	1	1	1	40	40
Total						6,674,040

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

Dated: January 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1275 Filed 1–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Notice of Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 23, 2011, the comment period for the notice of public meeting entitled Generic Drug User Fee; Public Meeting; Request for Comments, published in the **Federal Register** of August 9, 2010 (75 FR 47820). In that notice, FDA announced a public meeting that took place on September 17, 2010, to gather stakeholder input on the development of a generic drug user fee program. FDA is reopening the comment period to permit public consideration of late-received comments and to provide an opportunity for all interested parties to provide information and share views on the matter.

DATES: Submit either electronic or written comments by February 23, 2011.

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: Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993. 301–796–4830. *FAX:* 301–847–3541. *e-mail: peter.beckerman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2010 (75 FR 47820), FDA published a notice of a public meeting on the development of a generic drug user fee program. In that notice, FDA posed several questions related to a user fee for human generic drugs, and sought public input on such a program. The Agency received submissions and presentations from the public meeting, which are now posted on FDA's Web site. In the **Federal Register** of November 4, 2010 (75 FR 67984), FDA subsequently reopened the comment period for 30 days to allow consideration of submissions received after the original docket closing date. Because FDA has since received multiple requests to reopen the docket, including requests from generic industry segments that did not previously comment, FDA has decided to reopen the docket to permit public input on all the submissions.

Interested persons were originally given until October 17, 2010, to comment on the development of a generic drug user fee program. FDA is now reopening the docket to permit comment until February 23, 2011.

II. Request for Comments

FDA has received several requests to allow interested persons additional time to comment. The requesters represent manufacturers of active pharmaceutical ingredients who did not previously respond to FDA's specific requests for comments. In light of these requests, FDA is reopening the comment period for an additional 30 days.

III. How To Submit Comments

Regardless of attendance at the public meeting interested persons may submit either electronic or written comments to the Division of Dockets Management (*see* **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: January 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1274 Filed 1–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0620]

The National Antimicrobial Resistance Monitoring System Strategic Plan 2011–2015; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of a document for The National Antimicrobial Resistance Monitoring System (NARMS) entitled "NARMS Strategic Plan 2011–2015." The document outlines the strategic goals and objectives for 2011 through 2015 of the NARMS program developed by the participating Agencies (FDA, the Centers for Disease Control and Prevention (CDC), and the United States Department of Agriculture (USDA)) based on recommendations of an External Subcommittee of the Science Board to FDA. The Agency is soliciting public comment on the goals and objectives in the Strategic Plan and whether the goals and objectives meet the recommendations of the subcommittee.

DATES: Submit either electronic or written comments by March 25, 2011.

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: Patrick McDermott, Center for Veterinary Medicine (HFV–530), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708. 301–210–4213. *e-mail: patrick.mcdermott@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

NARMS is a national public health surveillance program that monitors the susceptibility of enteric bacteria to antimicrobial agents of medical importance. The NARMS program, established in 1996, is a collaboration between FDA, CDC, USDA, and State and local health departments. NARMS also has established collaborations with scientists and surveillance systems monitoring antimicrobial resistance in other countries.

Foodborne diseases are an important cause of morbidity and mortality worldwide. Travel, migration, and distribution of contaminated food contribute to the problem of foodborne diseases. Non-typhoidal *Salmonella* and *Campylobacter* are the leading bacterial causes of foodborne illness in the United States and many countries. Each year over two million people in the United States are infected with these bacteria, resulting in tens of thousands of hospitalizations and hundreds of deaths. Certain populations, such as young children (<5 years), the elderly, and the immunocompromised, are at higher risk for infection. Most *Salmonella* and *Campylobacter* infections are self-limited, but antimicrobial agents are essential to treat severe illness. Antimicrobial resistance occurs among bacterial foodborne pathogens and is recognized as a global public health hazard. NARMS monitors antimicrobial susceptibility in enteric bacteria from humans, retail meats, and food-producing animals. The human isolate component of NARMS was initiated in 1996, and at that time tested only non-typhoidal *Salmonella* and *Escherichia coli* O157 isolates. In 1997, testing of *Campylobacter* isolates began, followed by *Salmonella* serotype Typhi and *Shigella* in 1999. The animal component of NARMS started in 1997, with monitoring of *Salmonella* isolated from chicken, turkey, cattle, and swine carcasses, and later expanded to include *Campylobacter* (1998), *E. coli* (2000), and *Enterococcus* (2003) isolated from chicken carcasses. The retail meat component of NARMS started in 2002 with testing of *Salmonella, Campylobacter, E. coli,* and *Enterococcus* isolates from meat commodities sold in retail stores.

In addition to monitoring, NARMS conducts epidemiologic and microbiologic research studies. Some studies examine risk factors and clinical outcomes of infections with specific bacterial serotypes or subsets of bacteria that exhibit particular resistance patterns. NARMS research studies also focus on understanding the genetic mechanisms of antimicrobial resistance in enteric bacteria and the mechanisms that permit the transfer of resistance