WILLKIE FARR & GALLAGHER LLP

787 Seventh Avenue
New York, NY 10019-6099
Tel: 212 728 8000
Fax: 212 728 8111

May 19, 2006

VIA FIRST-CLASS MAIL

U.S. Department of Health and Human Services
Deputy Assistant for Public Affairs (Media)
Room 17A46
5600 Fishers Lane
Rockville, Maryland 20857

Re: **Freedom of Information Act Appeal**
Reference No. 06-2876

Dear Sir or Madam:

This firm represents Bloomberg News ("Bloomberg") in connection with Bloomberg's above-referenced Freedom of Information Act[1] ("FOIA") request (the "Request"). I am writing on behalf of Bloomberg to appeal: (1) the failure of the Food and Drug Administration (the "FDA") to respond to the Request in a timely manner; and (2) the denial of expedited processing for the Request. I enclose herewith a copy of Bloomberg's Request and the FDA's denial of expedited processing (signed by Julie Zawisza) dated April 19, 2006 (the "FDA Expedited Processing Denial").[2]

BACKGROUND TO THE REQUEST

The Request derives from significant public concerns about potential side effects -- in particular, suicidal thoughts and actions[3] -- of Neurontin (chemical name: gabapentin), an anti-epileptic drug originally sold by Parke-Davis, which was later acquired by Pfizer, Inc. ("Pfizer"). These concerns are

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1 5 U.S.C. § 552, *et seq.*

2 Copies of the Request and the FDA Expedited Processing Denial are enclosed. Although the FDA Expedited Processing Denial was issued by the Department of Health and Human Services -- under whose rubric the FDA resides -- for the sake of clarity, this letter will refer to its institutional author as the FDA.

3 The official website for Neurontin does not list suicidal thoughts and actions as potential side effects of the drug. *See* http://www.neurontin.com/.

heightened by the regular use of Neurontin for off-label purposes, including the treatment of, among other things, bipolar disorder, attention-deficit disorder, migraine headaches and restless leg syndrome. Indeed, on May 14, 2004, Pfizer pleaded guilty in federal court to criminal fraud charges for the unlawful promotion and marketing of Neurontin, agreeing to pay $430 million in settlement. According to the Government, Pfizer's "illegal and fraudulent promotion scheme corrupted the information process relied on by doctors in their medical decision making, thereby putting patients at risk."[4]

Although Pfizer settled its criminal case, it continues to market Neurontin. Additionally, Neurontin is now available in generic form, as are other anti-epileptic drugs, such as Topamax (chemical name: topiramate) and Lyrica (chemical name: pregabalin).

The public has a right to know what potential side effects it may experience as a result of taking Neurontin, Topamax, Lyrica or other anti-epileptic drugs, particularly if they are prescribed for off-label uses. (It is not illegal for a doctor to prescribe a medication for an off-label use; it is illegal for a company to market that medication for an off-label use.) Part and parcel of the public's right is understanding what the FDA knew about these potential side effects, when and how the FDA uncovered these potential side effects, and the forthrightness of pharmaceutical companies to the FDA about these potential side effects. The investing public, moreover, has an additional interest in the potential civil liability of various pharmaceutical companies deriving from the alleged side effects, particularly as related to off-label use.

THE REQUEST

On February 2, 2006 Bloomberg requested copies, pursuant to FOIA, of:

> 1. Any correspondence from Russell Katz of FDA to Pfizer dated on or about March 16, 2005 requesting data regarding suicidal thoughts or actions triggered by Neurontin (chemical name: gabapentin);
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> 2. Any correspondence dated from January 1, 2004 to present, from the FDA to manufacturers of other medications including Topamax (chemical name: topiramate), Lyrica (chemical name: pregabalin) and other anti-epileptic drugs regarding suicidal thoughts or actions triggered by those chemicals;
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> 3. Letters and other material submitted to FDA by manufacturers of Neurontin, Topamax, Lyrica and other anti-epileptic drugs in response to letters from Russell Katz and any other requests by FDA for data on the development of suicidal thoughts and actions by patients taking

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[4] Bernadette Tansey, *Huge Penalty In Drug Fraud: Pfizer Settles Felony Case In Neurontin Off-Label Promotion*, SAN FRANCISCO CHRONICLE, May 14, 2004, at C1.

Neurontin, Topomax, Lyrica and other anti-epileptic drugs during clinical trials or during the post-marketing period.

(Together, the "Requested Documents.") Additionally, Bloomberg requested expedited processing of the Request.

THE FDA'S FAILURE TO RESPOND

The FDA was required to "determine within 20 [business] days . . . after the receipt of [the Request] whether to comply with [the Request] and . . . notify [Bloomberg] of such determination and the reasons therefore." 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b). Because the FDA received the Request on February 28, 2006, this deadline was March 28, 2006. Upon notice to Bloomberg, the FDA could have extended this deadline by no more than ten business days, or until April 11, 2006. *See* 5 U.S.C. § 552(a)(6)(B)(i); 21 C.F.R. § 20.41(b)(3)(i)(A). The FDA never provided such notice.

The FDA, moreover, was required to respond to Bloomberg's request for expedited processing no later than March 10, 2006. *See* 21 C.F.R. § 20.41(c).

To date, the FDA has not responded ***at all*** to the substance of the Request.

On April 19, 2006, more than a month after its deadline, the FDA responded to Bloomberg's request for expedited processing, summarily denying expedition, stating that Bloomberg had not "demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." FDA Expedited Processing Denial.

Following the FDA Expedited Processing Denial, Rob Waters, a reporter for Bloomberg, spoke with a member of the Department of Health and Human Services' FOIA staff (the "HHS FOIA Staffer"), who told Mr. Waters that the FDA would take approximately one year to process the Request.

ARGUMENT

First, the FDA's failure to respond to the substance of the Request served as a constructive denial of the Request. *See, e.g., Tripp v. Department of Defense*, 193 F. Supp. 2d 229, 233 (D.D.C. 2002). The HHS FOIA Staffer's statement, moreover, that the FDA would take approximately one year to process the Request presents a clear violation of the timing requirements of both FOIA and the FDA's own regulations. *See* 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

Beyond the requirements of both statute and regulation, the FDA's inexcusable delay harms the public: (1) The public needs to know the potential health effects of widely-prescribed medications; allegations of negative side effects, if true, could pose a significant risk to anybody taking the medications, particularly off-label. (2) The public must understand how the FDA has addressed this potential health crisis -- such information sits at the very core of the public's faith in the FDA and its role as the primary regulator of pharmaceuticals in the country.

The Requested Documents must be disclosed pursuant to FOIA. They do not fall within any of the recognized exceptions to FOIA. Accordingly, we request that the FDA provide Bloomberg with the Requested Documents as soon as possible.

Second, the FDA improperly denied Bloomberg's request for expedited processing. As the FDA admitted in the FDA Expedited Processing Denial, the FDA must grant Bloomberg's request for expedited processing where the request is made by "a person primarily engaged in disseminating information, [with an] urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). All three prongs of this test are met: (1) Bloomberg is a major news organization, and the request was made by a Bloomberg reporter. (2) There is an urgency to inform the public: people lives are, quite literally, at risk if they do not readily grasp both the potential side effects of certain pharmaceuticals, and the FDA's understanding of, and investigation into, those same potential side effects. (3) The Requested Documents directly address FDA activity with respect to certain anti-epileptic drugs.

Accordingly, we request that the FDA expedite the processing of the Request and the search for, and delivery of, the Requested Documents.

It is not Bloomberg's intention or desire to burden the FDA unnecessarily, and if there is a way to ease any burden, we would be happy to explore it with you. In the meantime, we are compelled to ask you to consider this appeal as quickly as possible.

Please feel free to contact me directly at 212-728-8616 if you have any questions regarding Bloomberg's appeal.

Very truly yours,

Michael D. Maimin

Enclosures

cc: Julie Zawisza, Department of Heath and Human Services
Charles J. Glasser, Esq.