

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CARETOLIVE, etc.	:	
	:	
Plaintiff,	:	Case No. C2-07-729
	:	
v.	:	JUDGE FROST
	:	
ANDREW VON ESCHENBACH, etc.	:	Magistrate Judge King
et al.	:	
	:	
Defendants.	:	

**DEFENDANTS’ RESPONSE IN OPPOSITION TO
PLAINTIFF’S MOTION FOR ORDER THAT FDA COMPLY
WITH FREEDOM OF INFORMATION ACT**

INTRODUCTION

On July 30, 2007, Plaintiff CareToLive (“CTL”) filed this lawsuit asserting a host of claims against various officials of the Food and Drug Administration (“FDA”) and challenging the agency’s failure to grant immediate approval to a biologics license application (“BLA”) for Provenge, a biological product intended to treat a particular type of metastatic prostate cancer. After an informal conference on August 29, 2007, the Court ordered CTL to file an amended complaint “that clearly and specifically sets forth its causes of action so that both the Court and Defendants can understand the nature of the claims Plaintiff seeks to pursue.” (Doc. 20). CTL filed an amended complaint on September 5, 2007, again asserting a variety of constitutional, statutory, and declaratory claims. Notably, neither the original nor the amended complaint alleged a claim under the Freedom of Information Act (“FOIA”).

Also during the August 29, 2007 informal conference, the government objected to CTL’s repeated efforts to obtain discovery in this lawsuit, arguing among other things, that discovery

was at the very least premature pending the resolution of Defendants' then-forthcoming motions to dismiss and, more importantly, that this case is governed by the Administrative Procedure Act ("APA"), which provides for judicial review only of the administrative record. After CTL refused to agree to a stay of discovery, this Court opined that the government could file a motion for protective order. The government filed such a motion on September 12, 2007 (Doc. 26), and it is fully briefed and pending.

Despite the pendency of that motion, CTL has now filed a motion seeking to compel FDA to produce documents responsive to a FOIA request sent by CTL to FDA's Cincinnati District Office after this lawsuit was filed. CTL's request was received by FDA's Division of Freedom of Information ("DFOI") in Rockville, Maryland, on September 11, 2007. *See* Exhibit A. It was assigned number 2007-8316, indicating that it was the 8,316th FOIA request received by FDA in calendar year 2007. On the same day, FDA sent a letter acknowledging receipt of the request and stating that it would respond as soon as possible. *See* Exhibit B. CTL's FOIA request seeks letters written to FDA from Drs. Scher, Hussain, and Fleming regarding the Provenge BLA, including the envelopes or other documents transmitting those letters to FDA and to any media outlets, including a publication called "The Cancer Letter." *See* Exhibit A.

This Court lacks jurisdiction to grant relief under FOIA. In addition, CTL's motion was premature, demonstrates CTL's continuing disregard for procedural requirements, and is a transparent attempt to circumvent the APA scope of review and the discovery rules. Accordingly, the motion should be denied.

ARGUMENT

I. THE COURT LACKS JURISDICTION TO CONSIDER PLAINTIFF'S MOTION, BECAUSE FOIA AUTHORIZES JUDICIAL RELIEF ONLY UPON FILING OF A COMPLAINT

FOIA provides that:

On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.

5 U.S.C. § 552(a)(4)(B) (emphasis added). Thus, under the plain language of the statute, a court does not have jurisdiction to order an agency to produce records pursuant to a FOIA request until a *complaint* has been filed under FOIA. *See also North v. Walsh*, 881 F.2d 1088, 1094 (D.C. Cir. 1989) (“The statutory language [of FOIA], however, clearly requires that a person seeking disclosure of information, after recourse to an administrative process, file a complaint to trigger court action.”); *Thompson v. Walbran*, 990 F.2d 403, 405 (8th Cir. 1993) (per curiam) (affirming dismissal of FOIA claims in prisoner *Bivens* lawsuit in part because the plaintiff “did not seek production of the documents and records *in his complaint*”) (emphasis added); *Lucabaugh v. IRS (In re Lucabaugh)*, 262 B.R. 900, 905 (E.D. Pa. 2000) (“Congress [intended] that a separate complaint be filed under FOIA before a federal court obtains jurisdiction to enjoin a withholding of official information. To hold to the contrary would give undue precedent to FOIA request[s] in aid of discovery over all other FOIA requests.”) (quoting *Lincoln Nat’l Bank v. Lampe*, 421 F. Supp. 346, 349 (N.D. Ill. 1976)).

CTL briefly acknowledges this basic jurisdictional requirement in its motion, but apparently chose not to comply, claiming that “[w]hile this matter could be filed as part of an

amended complaint or separate complaint, considering the complexity of the underlying complaint a motion seemed more appropriate to bring this to the attention of the court, as it is related to this ongoing litigation.” CTL Mot. at 2. Contrary to CTL’s assertions, CTL’s failure to adhere to the requirements of FOIA is fatal to its motion. Because CTL did not comply with FOIA and raise its FOIA claim in its complaint or amended complaint, this Court lacks jurisdiction to grant relief under FOIA and must deny CTL’s motion.

Moreover, CTL is mistaken in its assertion that this matter could be raised as part of an amended complaint in this action. Because CTL has already amended its complaint prior to the filing of defendants’ motions to dismiss, it must seek (and be granted) leave of Court prior to any further amendment. *See* Fed. R. Civ. P. 15(a). Should CTL seek leave to do so, however, such a request should be denied because the proposed amendment “would radically alter the scope and nature of the case and bears no more than a tangential relationship to the original action.” *Miss. Ass’n of Coops. v. Farmers Home Admin.*, 139 F.R.D. 542, 544 (D.D.C. 1991) (citing *Caton v. Barry*, 500 F. Supp. 45, 52 (D.D.C. 1980); second citation omitted).

In *Mississippi Ass’n of Cooperatives*, the court rejected a plaintiff’s attempt to combine a FOIA and an APA challenge. In that case, plaintiff brought suit under FOIA seeking agency documents related to claims of race discrimination. *Id.* at 542. Several months later, after much of the FOIA claim had been litigated, plaintiff sought to amend the complaint to add APA and civil rights claims. *See id.* The court rejected the plaintiff’s argument that the claims were related because the civil rights and APA allegations would be based on the content of documents discovered in the FOIA proceedings, explaining that while the FOIA action involved the plaintiff’s access rights to government documents and the government’s rights to withhold such

documents under certain circumstances, the contents of the documents were relevant to the FOIA action only to the extent that they bore on public disclosure. *Id.* at 544. The court reasoned that whatever other issues the contents may raise, “such issues are not related legally or factually to the FOIA action.” *Id.* The court then denied the plaintiff’s motion for leave to amend because the proposed new civil rights and APA claims, “have no relationship to the original [FOIA] suit and amendment of the complaint in this regard would radically shift the scope and nature of the litigation. Because the complaint, as amended, would be so different it cannot be said that leave to amend in this case would promote judicial economy.” *Id.* at 545; *see also Szymanski v. DEA*, No. 93-1314, 1993 U.S. Dist. LEXIS 14574, at *5-*7 (D.D.C. Oct. 5, 1993) (striking plaintiff’s amended complaint because it sought to add claims and parties that were unrelated to a straightforward FOIA dispute).

As in *Mississippi Ass’n of Cooperatives*, CTL’s request for FOIA relief is unrelated to the APA and other claims raised in CTL’s complaint and amended complaint. FOIA deals only with whether the documents must be publicly released or whether FDA can withhold them under an exemption, while the claims raised in this lawsuit will require this Court to determine whether it has jurisdiction to consider CTL’s claims, and, if so, whether FDA was arbitrary and capricious in declining to approve the Provenge BLA at this time. Thus, as in *Mississippi Ass’n of Cooperatives*, this Court should reject CTL’s claim that it could insert an unrelated FOIA claim into this lawsuit by seeking leave to file a second amended complaint. To obtain relief under FOIA, CTL must file a proper FOIA *complaint* in a separate lawsuit.

As set forth in Defendants’ Motion for Protective Order (Doc. 26), CTL is not entitled to discovery at this time or indeed, at all, in this APA lawsuit. “The task of the reviewing court is

to apply the appropriate APA standard of review ... to the agency decision based on the record the agency presents to the reviewing court.” *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). The APA does not provide for review of extra-record evidence; it operates as a bar to discovery by requiring the court to look no further for evidence than the administrative record on which the agency based its decision. *See IMS, P.C. v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997) (“If a court is to review an agency’s action fairly, it should have before it neither more nor less information than did the agency when it made its decision.”) (internal quotation marks and citation omitted).

In this case, CTL filed its FOIA request after initiating this lawsuit and after CTL failed to obtain similar documents by improperly issuing subpoenas to “The Cancer Letter.” The instant motion is merely a transparent attempt to avoid the prohibition on discovery in an APA review matter and should be rejected.

II. PLAINTIFF’S FAILURE TO ALLOW ADMINISTRATIVE EXHAUSTION BY FILING A PREMATURE MOTION DEPRIVES THIS COURT OF JURISDICTION

CTL’s motion is also fatally flawed because CTL filed it before the twenty-day period for FDA’s response expired. Even a plaintiff that properly seeks relief by filing a *complaint* under FOIA (rather than a *motion* in a case not brought under FOIA) must exhaust its administrative remedies before filing suit. Filing a premature complaint deprives the Court of jurisdiction.

FOIA provides that a requester will be deemed to have exhausted administrative remedies if the agency does not process a FOIA request within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the *receipt* of any such request. *See* 5 U.S.C. § 552(a)(6)(A), (C). The government does not know when CTL mailed its request to FDA’s

Cincinnati District Office, and that date is not relevant here. However, it is notable that CTL failed to send its request to the correct recipient. Pursuant to 5 U.S.C. § 552(a)(1)(A), FDA has published in the *Federal Register*, as codified at 21 C.F.R. § 20.30, the employees from whom, and the methods whereby, the public may obtain information. CTL failed to send its request to FDA's FOI staff in Rockville, Maryland, as explicitly required by 21 C.F.R. § 20.30, and instead addressed it to FDA's Cincinnati District Office (a particularly inappropriate destination considering that the requested documents include and relate to letters that were supposedly circulated at FDA in Maryland and to a publication based in the District of Columbia).

Although CTL's request is dated August 15, 2007, the correct recipient, DFOI, did not *receive* it until September 11, 2007. *See* Exhibit A. (FDA advised CTL of *receipt* the same day. *See* Exhibit B.) Accordingly, FDA was required to respond by October 10, 2007. CTL, however, filed this motion on September 28, 2007, well before its administrative remedies were exhausted.

It is well understood that a FOIA requestor must exhaust the available administrative remedies under FOIA before it may seek relief in the federal courts. *Oglesby v. United States Dep't of the Army*, 920 F.2d 57, 61-62 (D.C. Cir.1990). A premature filing of a FOIA claim that has not matured because a party failed to exhaust mandatory administrative remedies prior to filing its complaint "is subject to dismissal for lack of subject matter jurisdiction." *Judicial Watch, Inc. v. U.S. Naval Observatory*, 160 F. Supp. 2d 111, 112 (D.D.C. 2001). The rationale behind the exhaustion requirement is that it gives the agency "an opportunity to exercise its discretion and expertise on the matter and to make a factual record to support its decision." *Oglesby*, 920 F.2d at 61 (citing *McKart v. United States*, 395 U.S. 185, 194 (1969)). Moreover,

it allows agency supervisors an opportunity to correct mistaken denials of meritorious FOIA requests, thereby obviating the need for judicial review by the courts. *Id.* Even if CTL had sought judicial relief by *complaint*, rather than by motion, this Court would be obliged to dismiss such a premature complaint for lack of subject-matter jurisdiction. *U.S. Naval Observatory*, 160 F. Supp. 2d at 113; *Judicial Watch, Inc. v. FBI*, No. Civ.A. 01-1216 (RBW), 2002 WL 34339771, at *4 (D.D.C. July 26, 2002). Nor can CTL be heard to assert that this Court has jurisdiction by contending that although its motion was premature, FDA nonetheless did not respond properly within the required time period. *U.S. Naval Observatory*, 160 F. Supp. 2d at 113; *Judicial Watch, Inc. v. FBI*, No. Civ.A. 01-1216 (RBW), 2002 WL 34339771, at *4 (D.D.C. July 26, 2002) (dismissing prematurely-filed FOIA complaint for lack of subject-matter jurisdiction, and finding that Court did not retroactively acquire subject-matter jurisdiction if agency still had not responded by end of statutory time period: “the Court will only consider those facts and circumstances that existed at the time of the filing of the complaint, and not subsequent events”); *cf. Dorn v. Comm’r*, No. 2:03-cv-539, 2005 U.S. Dist. LEXIS 12921 (M.D. Fla. May 12, 2005) (dismissing lawsuit where complaint was filed prematurely, even though agency ultimately responded after 20 day period).

III. CTL’S FOIA DEMAND, EVEN IF SUBMITTED BY COMPLAINT AFTER ADMINISTRATIVE EXHAUSTION, WOULD HAVE TO BE REJECTED BECAUSE FOIA PROVIDES RELIEF ONLY AGAINST AN AGENCY AND NOT INDIVIDUALS

In addition, CTL cannot obtain relief under FOIA against these Defendants, who are current or former employees of FDA and the Department of Health and Human Services. Neither the agency head nor other agency officials are proper parties to a FOIA suit; the only proper defendant is the agency itself. *See* 5 U.S.C. § 552(a)(4)(B) (granting district courts

“jurisdiction to enjoin the *agency* from withholding agency records and to order the production of any agency records improperly withheld from the complainant”) (emphasis added); *Thompson*, 990 F.2d at 405 (affirming dismissal of FOIA claims brought against individual employee; “FOIA authorizes suit against federal agencies and does not create [a] cause of action against individual employees of the agency.”) (internal quotation marks and citation omitted); *Petrus v. Bowen*, 833 F.2d 581, 582 (5th Cir. 1987) (same; “Neither the Freedom of Information Act nor the Privacy Act creates a cause of action for a suit against an individual employee of a federal agency.”); *Jefferson v. Reno*, 123 F. Supp. 2d 1, 3 (D.D.C. 2000) (approving plaintiff’s voluntary agreement to dismiss individual employee from FOIA claim; “Individual federal officials are not proper defendants in a FOIA action because it is the agency’s responsibility to produce records.”). For this reason too, this Court cannot grant the relief requested by CTL.

IV. FDA SHOULD BE PERMITTED TO PROCESS PLAINTIFF’S FOIA REQUEST IN THE ORDER THAT IT WAS RECEIVED

CTL claims that it has “an absolute right to the information,” arguing that the documents sought in the FOIA request are related to the claims in this lawsuit and that “[w]hile it may seem premature to file such a request, this is an emergency case and time is of the essence.” CTL Mot. at 2, 4.

As the Supreme Court has recognized, however, CTL has no special rights under FOIA simply because it is a party in litigation. *See NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n. 10 (1975) (a party’s rights under FOIA “are neither increased nor decreased by reason of the fact that it claims an interest in [withheld materials] greater than that shared by the average member of the public. [FOIA] is fundamentally designed to inform the public about agency action and not to benefit private litigants.”); *see also John Doe Agency v. John Doe Corp.*, 493

U.S. 146, 153 (1989) (“FOIA was not intended to supplement or displace the rules of discovery.”) (citing *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 236-239, 242 (1978)). Each FDA component that may have responsive documents must therefore be permitted to process CTL’s request in the same manner as it processes all other FOIA requests: in the order that it was received, in accordance with the agency component’s first-in, first out processing system. *See* 21 C.F.R. § 20.43(d).

Although a requester will be deemed to have exhausted administrative remedies if the agency does not process its FOIA request within twenty business days, *see* 5 U.S.C. § 552(a)(6)(A), (C), Congress anticipated that agencies might not be able to reach a determination within that time period. Thus, to prevent the deadlines for responding to FOIA requests from becoming “rigid and unworkable, Congress inserted a special ‘safety valve’” into the statute. *Appleton v. FDA*, 254 F. Supp. 2d 6, 8 (D.D.C. 2003); *see also Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 610 & n.11 (D.C. Cir. 1976). If “the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records.” 5 U.S.C. § 552(a)(6)(C)(i). (This provision presumes, of course, that a court has jurisdiction in the first place, *i.e.*, that a properly exhausted claim is presented to the court by *complaint* rather than by *motion*.)

Pursuant to § 552(a)(6)(C)(i), courts have granted agencies a stay of FOIA litigation in order to allow them to process subject FOIA requests on a first-in, first-out basis if (1) the agency is deluged with a volume of requests for information vastly in excess of that anticipated by Congress; (2) the existing agency resources are inadequate to deal with the volume of such

requests within the time limits established by § 552(a)(6)(C); and (3) the agency can show that it is exercising due diligence in processing the requests. *See Open America*, 547 F.2d at 616; *see also Edmond v. U.S. Attorney*, 959 F. Supp. 1, 3 (D.D.C. 1997) (citing cases and stating that courts have almost “uniformly granted the government reasonable periods of time in which to review FOIA requests when there is a backlog”).

Congress explicitly endorsed the D.C. Circuit’s approach in *Open America* when it enacted the Electronic Freedom of Information Act Amendments of 1996. Congress clarified that the “exceptional circumstances” provision of subsection (a)(6)(C) encompasses an agency’s routine and predictable administrative backlog of FOIA requests, so long as “the agency demonstrates reasonable progress in reducing its backlog of pending requests.” 5 U.S.C. § 552(a)(6)(C)(ii). As the legislative history makes clear, Congress deemed this amended subsection “consistent” with *Open America*’s interpretation of the “exceptional circumstances” requirement. H.R. Rep. No. 104-795, 1996 U.S.C.C.A.N. 3448, 3467 (Sept. 17, 1996).

An agency demonstrates due diligence when it complies with “all lawful demands under [FOIA] in as short a time as is possible by assigning all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown.”¹ *Open America*, 547 F.2d at 616. As

¹ Pursuant to 5 U.S.C. § 552(a)(6)(E)(i), expedited *agency* processing of a FOIA request is warranted only upon a demonstration of “compelling need,” which requires a requestor to establish “(I) that a failure to obtain requested records on an expedited basis . . . could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or (II) with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.” 5 U.S.C. § 552(a)(6)(E)(v). CTL has not demonstrated that the failure to obtain letters, the substance of which have already been publicly disclosed, could reasonably be expected to pose an imminent threat to any individual, nor is CTL “a person primarily engaged in disseminating information.”

the D.C. Circuit explained, permitting FOIA requestors who file complaints to jump to the head of the queue would wreak an injustice on other, non-litigious FOIA requestors, as well as result in conflicting demands on finite agency resources:

[E]ven those with the dimmest of eyesight could look ahead a few months and see that the regulation of priorities in all agencies ... would very shortly become the function of the courts. If everyone could go to court when his request had not been processed within thirty days, and by filing a court action automatically go to the head of the line at the agency, we would soon have a listing based on priority in filing lawsuits, i.e., first into court, first out of the agency.

. . . [S]urely others with a desire equal to plaintiffs here would not have the financial resources to hire a lawyer and go to court, which would create a further invidious and unintended distinction.

Open America, 547 F.2d at 615. Other courts have similarly abstained from ordering agencies to process FOIA requests out of turn. *See Donham v. U.S. Dep't of Energy*, 192 F. Supp. 2d 877, 883 (S.D. Ill. 2002) (“granting a preference to litigants over other FOIA requestors would result in an unfair and inefficient first to sue, first served system”); *Freeman v. U.S. Dep't of Justice*, 822 F. Supp. 1064, 1067 (S.D.N.Y. 1993) (first-in, first-out is the “fairest method for processing requests that are not urgent”); *see also* H.R. Rep. No. 104-795, 1996 U.S.C.C.A.N. at 3466 (stating that processing requests on a first-in, first-out basis, coupled with a multi-track processing system, constitutes due diligence).

FDA employs over 9,000 employees around the country and regulates the manufacture and distribution of more than \$1 trillion worth of goods annually. *See* FDA, *FDA Overview*, slide 15, www.fda.gov/oc/opacom/fda101/sld015.html. Commensurate with its size and the vast number of documents generated in the ordinary course of agency business, FDA receives an enormous volume of FOIA requests and has amassed a substantial backlog. As noted above, CTL’s FOIA request, received in September, was the 8,316th such request FDA has received this

year. FDA received 19,797 FOIA requests in fiscal year 2006, which were added to an outstanding backlog of 17,369 requests pending at the end of the previous fiscal year. FDA, *Freedom of Information Annual Report – 2006*, <http://www.fda.gov/foi/annual2006.html>. FDA components process requests on a first-in, first out basis. See 21 C.F.R. § 20.43(a) (“Each Food and Drug Administration component is responsible for determining whether to use a multitrack system to process requests for records maintained by that component”); 21 C.F.R. § 20.43(d) (“Requests assigned to a given track will ordinarily be processed on a first-in, first-out basis within that track”).

Courts have granted FDA a stay (in ripe FOIA claims presented by *complaint* after required administrative exhaustion) based on FDA’s showing of an enormous backlog of FOIA requests coupled with the FDA’s diligent efforts to reduce the backlog. See *Bower v. FDA*, No. Civ. 03-224-B-W, 2004 WL 2030277, at *2-*3, 2004 U.S. Dist. LEXIS 18369, at *5-*8 (D. Me. Aug. 30, 2004) (granting stay based on FDA’s representation to the court regarding the backlog and its efforts to reduce the backlog); *Appleton*, 254 F. Supp. 2d at 10 (granting stay in part based on FDA’s “good-faith, diligent effort to process the plaintiff’s request pursuant to FDA’s first-in, first-out complex track” and FDA’s “reasonable progress” in reducing its backlog).²

² *But see Weinberg v. von Eschenbach*, Civil Case No. 07-1819 (FSH) (D.N.J. October 10, 2007) (denying FDA stay motion in FOIA case without prejudice pending mediation; authorizing FDA to move again for stay with proper supporting evidence following mediation); *Bloomberg L.P. v. U.S. FDA*, 500 F. Supp. 2d 371 (S.D.N.Y. 2007) (denying FDA stay motion in FOIA complaint seeking expedited agency processing; decision issued on fact-specific grounds based upon national news organization’s demonstrating that, as a “person primarily engaged in disseminating information,” it had “compelling need” required by FOIA statute to be entitled to expedited agency processing).

Should this Court determine that it does have jurisdiction to consider CTL’s request for relief under FOIA, FDA respectfully requests an opportunity to file a full brief and supporting affidavits to demonstrate exceptional circumstances and due diligence pursuant to 5 U.S.C.

FDA should likewise be permitted to process CTL's FOIA request in the order that it was received. Any other outcome would be inequitable to the other FOIA requesters ahead of CTL who have not sought judicial relief and may lack the resources to do so.

§ 552(a)(6)(C)(i) and (ii).

CONCLUSION

For the foregoing reasons, Plaintiff's Motion for Order that FDA Comply with Freedom of Information Act should be denied.

Dated: October 19, 2007

Respectfully submitted,

Gregory G. Lockhart
United States Attorney

s/Mark T. D'Alessandro
Mark T. D'Alessandro (0019877)
Assistant United States Attorney
303 Marconi Blvd., Suite 200
Columbus, Ohio 43215
(614) 469-5715
Fax: (614) 469-5240
Email: mark.dalessandro@usdoj.gov

s/John J. Stark
John J. Stark (0076231)
Assistant United States Attorney
303 Marconi Blvd., Suite 200
Columbus, Ohio 43215
(614) 469-5715
Fax: (614) 469-5240
Email: john.stark@usdoj.gov

Eugene M. Thirolf
Director, Office of Consumer Litigation

s/Andrew Clark
Andrew Clark (Oklahoma Bar # 10760)
Trial Attorney, Office of Consumer
Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
(202) 307-0067
Fax: (202) 514-8742
E-mail: andrew.clark@usdoj.gov

s/Daniel K. Crane-Hirsch

Daniel K. Crane-Hirsch
(New York Bar # 4151015)
(Massachusetts Bar # 643302)
Trial Attorney, Office of Consumer
Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
(202) 616-8242
Fax: (202) 514-8742
E-mail: daniel.crane-hirsch@usdoj.gov

Of Counsel:

Jennifer Caruso
Attorney, Food and Drug Division
U.S. Department of Health & Human Services
Office of General Counsel
5600 Fishers Lane
Rockville, MD 20857

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Response was filed with the Court on this 19th day of October, 2007, using the Court's CM/ECF system, which will serve a copy on all counsel.

s/Mark T. D'Alessandro
Mark T. D'Alessandro (0019877)
Assistant United States Attorney