

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

CARETOLIVE,)	
a not-for-profit corp.,)	
)	Case No. 2:08-CV-0005
Plaintiff,)	
)	JUDGE FROST
v.)	
)	MAGISTRATE JUDGE KING
U.S. FOOD and DRUG)	
ADMINISTRATION,)	
)	
Defendant.)	

**DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION’S ANSWER
TO PLAINTIFF CARE TO LIVE’S COMPLAINT**

Defendant United States Food and Drug Administration (“FDA”) responds to Plaintiff CareToLive’s Complaint as follows:

COUNT I – Violation of Freedom of Information Act

1. The allegations in Paragraph 1 contain legal conclusions to which no response is required. To the extent a response is required, the allegations in Paragraph 1 are admitted, but it is denied that Plaintiff is entitled to any relief under FOIA.

2. Defendant admits receiving a FOIA request dated August 15, 2007, from Bellinger & Donahue, Attorneys at Law. Defendant denies the remainder of Paragraph 2 for lack of information.

3. Defendant admits that on September 11, 2007, the Division of Freedom of Information (“DFOI”), Office of Management Programs, Office of Management in the Office of the Commissioner (“OC”), FDA, received a Freedom of Information Act request dated August

15, 2007, from Bellinger & Donahue, Attorneys at Law, and assigned it number 2007-8316 (“FOIA request”). The remainder of Paragraph 3 is denied.

4. Defendant admits that FDA’s Center for Biologics Evaluation and Research (“CBER”) provided, by letter dated November 6, 2007, responsive documents to Plaintiff.

5. Defendant admits that on November 20, 2007, CBER informed Plaintiff that FDA’s Center for Drug Evaluation and Research (“CDER”) and OC would also respond to Plaintiff’s FOIA request. Defendant admits that no documents from CDER have been transmitted to Plaintiff. DFOI notified Plaintiff by letter dated January 24, 2008, that OC has no responsive documents. The remainder of Paragraph 5 is denied.

6. Defendant admits only that CBER provided, by letter dated November 6, 2007, responsive documents to Plaintiff. To the extent Paragraph 6 presents Plaintiff’s opinions and conclusions, it requires no response. To the extent a response is required, Defendant denies the remainder of Paragraph 6 for lack of information; CDER, which processes FOIA requests on a first-in, first-out basis, has not yet searched for documents responsive to Plaintiff’s FOIA request.

7. Defendant admits that on November 20, 2007, CBER informed Plaintiff that CDER and OC would also respond to Plaintiff’s FOIA request. The remainder of Paragraph 7 is denied.

8. Defendant admits only that CBER provided, by letter dated November 6, 2007, responsive documents to Plaintiff. To the extent Paragraph 8 presents Plaintiff’s opinions and conclusions, it requires no response. To the extent a response is required, Defendant denies the remainder of Paragraph 8 for lack of information.

9. The allegations in Paragraph 9 are denied.

10. Paragraph 10 presents Plaintiff's legal conclusions and requires no response. To the extent a response is required, the allegations in Paragraph 10 are denied.

11. Defendant admits that CDER has not transmitted responsive documents to Plaintiff. DFOI notified Plaintiff by letter dated January 24, 2008, that OC has no responsive documents. The remainder of Paragraph 11 contains Plaintiff's legal conclusions, which require no response. To the extent a response is required, the remainder of Paragraph 11 is denied.

12. Defendant admits that DFOI received the FOIA request on September 11, 2007, and that DFOI confirmed receipt on the same date. Defendant denies the remainder of Paragraph 12 for lack of information.

13. Defendant admits that CDER has not transmitted to Plaintiff any written communications or documents responsive to the FOIA request. DFOI notified Plaintiff by letter dated January 24, 2008, that OC has no responsive documents.

14. Defendant admits that on December 31, 2007, CDER, by telephonic message, informed Plaintiff that the FOIA request would be processed according to FDA's first-in, first-out protocol. Defendant denies the remainder of Paragraph 14.

15. Paragraph 15 presents Plaintiff's legal conclusions and therefore requires no response. To the extent a response is required, the allegations in Paragraph 15 are denied.

16. Defendant admits that some documents provided by CBER pursuant to the FOIA request appear originally to have been "copied" (i.e., "cc"d) to FDA Commissioner von Eschenbach or CDER's Dr. Richard Pazdur.

17. Defendant denies for lack of information that there are documents responsive to

the request possessed by CDER; CDER, which processes FOIA requests on a first-in, first-out basis, has not yet searched for documents responsive to Plaintiff's FOIA request. It is denied that OC has responsive documents; DFOI notified Plaintiff by letter dated January 24, 2008, that OC has no responsive documents. The remainder of Paragraph 17 is denied.

18. Paragraph 18 contains opinions and conclusions of Plaintiff, alleges no facts, and presents Plaintiff's legal conclusions, and therefore requires no response. To the extent a response is required, the allegations in Paragraph 18 are denied.

19. Paragraph 19 contains Plaintiff's legal conclusions and therefore requires no response. To the extent a response is required, the allegations in Paragraph 19 are denied.

20. Defendant admits that on September 11, 2007, DFOI received a FOIA request dated August 15, 2007, from Bellinger & Donahue, Attorneys at Law, and assigned it number 2007-8316. Defendant admits that CDER has not provided documents responsive to the FOIA request. Defendant denies that OC has not responded to Plaintiff's FOIA request because DFOI notified Plaintiff by letter dated January 24, 2008, that OC has no responsive documents.

21. Regarding the "wherefore" clause of the Complaint, it is denied that Plaintiff is entitled to any relief.

22. Defendant denies each and every allegation in the Complaint not specifically addressed.

DEFENSES

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

Defendant faces exceptional circumstances and is exercising due diligence in responding to Plaintiff's request under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq. Accordingly, Defendant is entitled to a stay of proceedings pursuant to 5 U.S.C. § 552(a)(6)(C)(i) and will be filing a motion for a stay.

Third Defense

The documents sought by Plaintiff in its FOIA request may be subject to exemptions from disclosure by CDER under FOIA. See 5 U.S.C. § 552(b).

WHEREFORE, having fully answered, Defendant respectfully requests that this Court dismiss with prejudice Plaintiff's Complaint and award Defendant its expenses, attorneys fees, costs and such other relief as the Court deems just and proper.

Respectfully submitted,

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s/John J. Stark
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CERTIFICATE OF SERVICE

I certify that on February 4, 2008, I electronically filed a copy of the foregoing Answer to the Complaint of Plaintiff CareToLive with the Clerk of the Court using the CM/ECF system. Notice of this filing will be sent to Kerry M. Donahue by operation of the Court's electronic filing system.

s/John J. Stark
John J. Stark
Assistant United States Attorney