

Def.'s Mot. for Summ. J., Ex. 1 (Letter from H. Thomas to FDA, July 23, 2007) ("FOIA Request").

Using Biocine Sclavo's name and license number, defendant searched the FDA databases it deemed most likely to contain responsive documents: the FDA's Center for Biologic Evaluation and Research's (1) Regulatory Management System – Biologics Licensing Application database (and its predecessor database), (2) Document Accountability and Tracking System (and its predecessor database), and (3) records and files transferred to the federal records system. *See* Decl. of Susan Frantz-Bohn ¶¶ 1, 7, 8, 10, Feb. 12, 2009 ("Frantz-Bohn Decl.") (annexed to Def.'s Mot. for Summ. J.). These searches revealed that Biocine Sclavo had been issued licenses for thirteen biologics products, all of which were revoked by 1993. *Id.* ¶ 11. This search also established that in accordance with the Federal Records Act, all related records had been transferred to storage at a federal records center, *id.* ¶ 13, and that records relating to one license that was revoked in 1979 had since been destroyed in the normal course, *id.* ¶ 14. In response to defendant's request for "all documents relating to [Biocine] Sclavo," *id.* ¶ 13, the federal records center forwarded six boxes containing approximately 15,000 pages of documents, *id.* ¶ 15. Six FDA employees spent a total of more than 50 hours searching the six boxes of documents, and all documents were searched twice by different individuals. *Id.* ¶¶ 15-16. Because some of the documents were in Italian, they were also searched specifically for the Italian words for bank, bank account, bank note, and savings bank. *Id.* ¶ 17. The search located no documents containing the name and/or address of a bank used by Biocine Sclavo or its U.S. distributor. *Id.* ¶ 18. On this basis, defendant moved a second time for summary judgment.

In opposing defendant's motion for summary judgment, plaintiff raises two issues relating to the agency's search. First, citing 21 C.F.R. §§ 20.81 and 20.112 as authority, he asserts that a license applicant is required to submit the name and address of its U.S. bank, the very information he is seeking. Pl.'s Opp'n ¶¶ 4, 6. Apparently doubting the adequacy of the FDA's review of the records, plaintiff asks this Court to conduct an *in camera* review of the 15,000 pages of documents retrieved from the federal records center. *Id.* ¶ 8. In its reply, the FDA states that the regulations plaintiff cites do not support his contention and that an *in camera* review is unwarranted. *See* Def.'s Reply at 2-3. Second, plaintiff contends that the record does not establish whether defendant searched for records related to the particular U.S. distributor, VOCO, Inc. Pl.'s Opp'n ¶ 3. In reply, defendant merely repeats that it "did not find any documents containing the name and/or address of the bank used by Biocine Scavo or its U.S. distributor." Def.'s Reply at 2.

DISCUSSION

Under Rule 56 of the Federal Rules of Civil Procedure, a motion for summary judgment must be granted if the pleadings and evidence on file show that there is no genuine issue of material fact, and that the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). In a FOIA suit, an agency is entitled to summary judgment once it satisfies its burden of demonstrating that no material facts are in dispute and that it has conducted a search reasonably calculated to uncover all relevant information, *Weisberg v. Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984), which either has been released to the requestor or is exempt from disclosure. *Students Against Genocide v. Dep't of State*, 257 F.3d 828, 833 (D.C. Cir. 2001). To challenge such a showing, the non-moving party "must set forth

specific facts showing that there is a genuine issue for trial,” Fed. R. Civ. P. 56(e), that would permit a reasonable jury to find in his favor. *Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987).

To show that its search was reasonable, the agency must demonstrate that when “viewing the facts in the light most favorable to the requester, . . . [it] ‘has conducted a search reasonably calculated to uncover all relevant documents.’” *Steinberg v. United States Dep’t of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994) (quoting *Weisberg*, 745 F.2d at 1485). The agency must show that it used “methods which can be reasonably expected to produce the information requested.” *Oglesby v. Dep’t of the Army*, 920 F.2d 57, 68 (D.C. Cir. 1990); *see also Campbell v. United States Dep’t of Justice*, 164 F.3d 20, 27 (D.C. Cir. 1998). In assessing the reasonableness of the search, a court is guided by principles of reasonableness. *Oglesby*, 920 F.2d at 68. The reasonableness of a search is not determined by its results, but by the method of the search itself. *Weisberg*, 745 F.2d at 1485. A search need not be exhaustive. *Miller v. U.S. Dep’t of State*, 779 F.2d 1378, 1383 (8th Cir. 1986). “There is no requirement that an agency search every record system.” *Oglesby*, 920 F.2d at 68. An agency's failure to find a particular document does not undermine the determination that the search was adequate. *Wilber v. CIA*, 355 F.3d 675, 678 (D.C. Cir. 2004); *Nation Magazine, Washington Bureau v. United States Customs Serv.*, 71 F.3d 885, 892 n.7 (D.C. Cir. 1995). Rather,

the standard of reasonableness which we apply to agency search procedures . . . requires a search reasonably calculated to uncover the sought materials. . . . [T]he [agency] is not required . . . to account for documents which the requestor has in some way identified if it has made a diligent search for those documents in the places in which they might be expected to be found

Miller, 779 F.2d at 1384-85. However, “if the sufficiency of the agency’s identification or retrieval procedure is genuinely in issue, summary judgment is not in order.” *Weisberg*, 627 F.2d at 370.

The Biocine Sclavo Search and Review

Plaintiff, relying on 21 C.F.R. §§ 20.81 and 20.112, contends that Biocine Sclavo was required to submit the information he is seeking. Pl.’s Opp’n ¶¶ 4, 6. Given that defendant did not produce the information sought, plaintiff doubts both the adequacy of the search and the review of the documents that were located. The plain text of the regulations on which plaintiff relies, however, does not require a license applicant to submit the name and address of the applicant’s U.S. bank. *See* 21 C.F.R. §§ 20.81, 20.112. In fact, the cited regulations do not relate even remotely to such a requirement, and the Court is not aware of any such requirement.

Because plaintiff has not shown there is any reason to assume that the FDA ever had a record of the licensee’s U.S. bank, he has also not shown that there is any basis on which to doubt the thoroughness of defendant’s search of approximately 15,000 pages of documents. Consequently, plaintiff has neither identified a genuine issue of material fact on this point nor established that an *in camera* review is warranted. As plaintiff raises no other issues with respect to the search for records related to Biocine Sclavo, summary judgment will be granted with respect to the first portion of plaintiff’s FOIA request: “(1) the name and address of the bank where Biocine Sclavo, S.P.A., f/k/a Sclavo, S.P.A. conduct[s] its banking in Italy and the United States.” Def.’s Mot. for Summ. J., Ex. 1.

The VOCO, Inc. Search

Plaintiff also challenges defendant's search because it is not clear that defendant searched its databases for records related to VOCO, Inc. Pl.'s Opp'n ¶ 3. Indeed, defendant's sworn statement claims only that it searched by using Biocine Sclavo's name and license number. Frantz-Bohn Decl. ¶ 8. It does not claim that it searched for documents by using VOCO, Inc.'s name and does not explain why, in light of plaintiff's FOIA request, a search that did not use VOCO Inc.'s name as a search term was nonetheless one reasonably calculated to uncover all relevant information. Nor does defendant's reply squarely address plaintiff's challenge. It merely repeats that it "did not find any documents containing the name and/or address of the U.S. bank used by Biocine Sclavo or its U.S. distributor," among those documents it retrieved by using Biocine Sclavo's name and license number as search terms. *See* Def.'s Reply at 2. It may well be the case that defendant's search was reasonable, but defendant has not provided the information necessary to support such a determination. Accordingly, summary judgment will be denied without prejudice as to the second part of plaintiff's FOIA request:

(2) . . . the name and address where Biocine Sclavo's, SPA f/k/a Sclavo's, SPA sole United States Distributor:
VOCO, INC., f/k/[a] SLAVO, INC.
5 Mansard Court
Wayne, New Jersey 07470
Fed. I.D. # 13-27712263
SIC # 5129
conduct[s] its bank transactions in the United States.

Def.'s Mot. for Summ. J., Ex. 1. Defendant will be required to supplement its declaration with respect to the reasonableness of its search for this information.

