U.S. District Court District of Maryland (Greenbelt) CIVIL DOCKET FOR CASE #: 8:23-cv-00489-DLB

AMA Systems, LLC et al v. U.S. Food and Drug Administration Date Filed: 02/22/2023

Assigned to: Judge Deborah L. Boardman

Cause: 05:552 Freedom of Information Act

Jury Demand: None

Nature of Suit: 895 Freedom of

Information Act

Jurisdiction: U.S. Government Defendant

Plaintiff

AMA Systems, LLC

represented by Madelaine Amanda Kramer Katz

Rifkin, Weiner, Livingston, LLC

4800 Hampden Lane

Suite 820

Bethesda, MD 20814 301-951-0150 Fax: 301-951-0172 Email: mkatz@rwllaw.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Marie Celeste Bruce

Rifkin, Weiner, Livingston, LLC

7700 Wisconsin Avenue

Suite 320

Bethesda, MD 20814 301-951-0150

Email: cbruce@rwllaw.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

Bluemar Promotions, LLC

represented by Madelaine Amanda Kramer Katz

(See above for address) **LEAD ATTORNEY**

ATTORNEY TO BE NOTICED

Marie Celeste Bruce

(See above for address) LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

Defendant

U.S. Food and Drug Administration

represented by Alicia Leigh Shelton

DOJ-USÃO

36 S. Charles Street

Fourth Floor

Baltimore, MD 21201

410-209-4836

Email: alicia.shelton2@usdoj.gov ATTORNEY TO BE NOTICED

Defendant

Robert M. Califf

in his official capacity as Commissioner of Food and Drugs Food and Drug Administration

represented by Alicia Leigh Shelton

(See above for address) ATTORNEY TO BE NOTICED

Interested Party

US Attorney MD EREK L BARRON

represented by Alicia Leigh Shelton (See above for address)

ATTORNEY TO BE NOTICED

Interested Party

US Attorney General MERRICK B GARLAND

represented by Alicia Leigh Shelton (See above for address)

ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
02/22/2023	1	COMPLAINT against U.S. Food and Drug Administration, Robert M. Califf (Filing fee \$ 402 receipt number AMDDC–10448695.), filed by Bluemar Promotions, LLC, AMA Systems, LLC. (Attachments: # 1 Civil Cover Sheet, # 2 Summons FDA, # 3 Summons Commissioner)(Kramer Katz, Madelaine) (Entered: 02/22/2023)
02/22/2023	2	Local Rule 103.3 Disclosure Statement by AMA Systems, LLC (Kramer Katz, Madelaine) (Entered: 02/22/2023)
02/22/2023	<u>3</u>	Local Rule 103.3 Disclosure Statement by Bluemar Promotions, LLC (Kramer Katz, Madelaine) (Entered: 02/22/2023)
02/23/2023	4	QC NOTICE: 1 Complaint, filed by Bluemar Promotions, LLC, AMA Systems, LLC was filed incorrectly. **Not all attorneys listed as counsel have signed the document. Court staff has entered the appearance of only the attorneys who have signed the document. All other attorneys must enter their own entries of appearance. (ybs, Deputy Clerk) (Entered: 02/23/2023)
02/23/2023	5	QC NOTICE: 1 Complaint, filed by Bluemar Promotions, LLC, AMA Systems, LLC was filed incorrectly. **The following attachments or exhibits are missing — Summons for the U.S. Attorney General and the U.S. Attorney for the District of Maryland. To correct this problem, file Summons for the U.S. Attorney General and the U.S. Attorney for the District of Maryland using the event Notice (Other) and link Summons for the U.S. Attorney General and the U.S. Attorney for the District of Maryland to 1. (ybs, Deputy Clerk) (Entered: 02/23/2023)
02/23/2023	6	NOTICE of Case Assignment. This case has been assigned to Magistrate Judge Gina L. Simms. AMA Systems, LLC, Bluemar Promotions, LLC or counsel for AMA Systems, LLC, Bluemar Promotions, LLC are required to review and comply with the Magistrate Judge Pilot Project Procedures which can be downloaded here . Pursuant to Standing Order 2019–07, which can be downloaded <a href="here</a">, counsel has 14 days from the date of this notice to file their consent, or decline to consent to proceed before a U.S. Magistrate Judge which can be downloaded <a href="here</a">. To file your consent, go to Civil > Other Filings > Other Documents > 25 Pct Mag - Consent to Proceed Before a Magistrate Judge. To file your declination, go to Civil > Other Filings > Other Documents > 25 Pct Mag - Decline to Proceed Before a Magistrate Judge. Failure to file a consent or declination will result in issuance of an Order to Show Cause. Please review the case management order that has been issued in this case. Magistrate Election Form due by 3/9/2023. (ybs, Deputy Clerk) (Entered: 02/23/2023)
02/23/2023	7	Case Management Order. Signed by Magistrate Judge Gina L Simms on 2/23/2023. (ybs, Deputy Clerk) (Entered: 02/23/2023)
02/23/2023	<u>8</u>	NOTICE of Appearance by Marie Celeste Bruce on behalf of AMA Systems, LLC, Bluemar Promotions, LLC (Bruce, Marie) (Entered: 02/23/2023)
02/23/2023	9	NOTICE by AMA Systems, LLC, Bluemar Promotions, LLC re <u>1</u> Complaint, Summons (U.S. Attorney General) (Bruce, Marie) (Entered: 02/23/2023)

02/23/2023	<u>10</u>	NOTICE by AMA Systems, LLC, Bluemar Promotions, LLC re 1 Complaint,
		Summons (U.S. Attorney for the District of Maryland) (Bruce, Marie) (Entered: 02/23/2023)
02/23/2023	<u>11</u>	Summons Issued 60 days as to Robert M. Califf, U.S. Food and Drug Administration, U.S. Attorney and U.S. Attorney General(ybs, Deputy Clerk) (Entered: 02/23/2023)
02/23/2023	<u>12</u>	SUMMONS Returned Executed by Bluemar Promotions, LLC, AMA Systems, LLC. Robert M. Califf served on 2/23/2023, answer due 4/24/2023; U.S. Food and Drug Administration served on 2/23/2023, answer due 4/24/2023. (Attachments: # 1 Exhibit 1 (Confirmation of Receipt), # 2 Exhibit 2 (Email Service Procedure – FDA))(Kramer Katz, Madelaine) (Entered: 02/23/2023)
03/08/2023	<u>14</u>	SUMMONS Returned Executed by Bluemar Promotions, LLC, AMA Systems, LLC. EREK L BARRON served on 2/24/2023, answer due 4/25/2023.(Kramer Katz, Madelaine) (Entered: 03/08/2023)
03/10/2023	<u>15</u>	SUMMONS Returned Executed by Bluemar Promotions, LLC, AMA Systems, LLC. MERRICK B GARLAND served on 3/6/2023, answer due 5/5/2023. (Attachments: # 1 Exhibit 1 (Return Receipt))(Kramer Katz, Madelaine) (Entered: 03/10/2023)
03/13/2023		Case Reassigned to Judge Deborah L. Boardman. Magistrate Judge Gina L Simms no longer assigned to the case. (kns, Deputy Clerk) (Entered: 03/13/2023)
03/24/2023	<u>17</u>	MOTION for Extension of Time to File Answer <i>or Respond to Complaint</i> by Robert M. Califf, U.S. Food and Drug Administration (Attachments: # 1 Text of Proposed Order)(Shelton, Alicia) (Entered: 03/24/2023)
04/06/2023	<u>18</u>	RESPONSE in Opposition re 17 MOTION for Extension of Time to File Answer <i>or Respond to Complaint</i> filed by AMA Systems, LLC, Bluemar Promotions, LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Kramer Katz, Madelaine) (Entered: 04/06/2023)
04/10/2023	<u>19</u>	ANSWER to 1 Complaint, by Robert M. Califf, U.S. Food and Drug Administration.(Shelton, Alicia) (Entered: 04/10/2023)
04/12/2023	<u>20</u>	MOTION for Other Relief <i>To Establish Summary Judgment Briefing Schedule</i> by Robert M. Califf, U.S. Food and Drug Administration (Attachments: # 1 Text of Proposed Order)(Shelton, Alicia) (Entered: 04/12/2023)
04/12/2023	21	PAPERLESS ORDER finding as moot <u>17</u> MOTION for Extension of Time to File Answer <i>or Respond to Complaint</i> . Defendants Califf and the FDA's answers were due April 24, 2023, and they filed timely a timely answer <u>9</u> . Signed by Judge Deborah L. Boardman on 4/12/2023. (lmys, Chambers) (Entered: 04/12/2023)
04/25/2023	<u>22</u>	RESPONSE in Opposition re <u>20</u> MOTION for Other Relief <i>To Establish Summary Judgment Briefing Schedule</i> filed by AMA Systems, LLC, Bluemar Promotions, LLC. (Attachments: # <u>1</u> Text of Proposed Order Proposed Order)(Kramer Katz, Madelaine) (Entered: 04/25/2023)
04/27/2023	23	PAPERLESS ORDER scheduling a status call for May 16, 2023 at 3:30 p.m. My chambers will circulate call—in information. Signed by Judge Deborah L. Boardman on 4/27/2023. (lmys, Chambers) (Entered: 04/27/2023)
05/16/2023		Telephone Conference re: status held on 5/16/2023 before Judge Deborah L. Boardman. (rc2s, Deputy Clerk) (Entered: 05/17/2023)
05/17/2023	<u>24</u>	ORDER granting 20 MOTION for Other Relief To Establish Summary Judgment Briefing Schedule. Signed by Judge Deborah L. Boardman on 5/17/2023. (ybs, Deputy Clerk) (Entered: 05/17/2023)
05/24/2023	<u>25</u>	MOTION for Summary Judgment by Robert M. Califf, U.S. Food and Drug Administration (Attachments: # 1 Memorandum in Support, # 2 Exhibit 1 (Kotler Declaration), # 3 Exhibit 2 (Davis Declaration), # 4 Text of Proposed Order)(Shelton, Alicia) (Entered: 05/24/2023)
06/07/2023	<u>26</u>	RESPONSE in Opposition re <u>25</u> MOTION for Summary Judgment filed by AMA Systems, LLC, Bluemar Promotions, LLC. (Attachments: # <u>1</u> Appendix Appendix of Exhibits, # <u>2</u> Exhibit 1, # <u>3</u> Exhibit 2, # <u>4</u> Exhibit 3, # <u>5</u> Exhibit 4, # <u>6</u> Exhibit 5, # <u>7</u>

		Exhibit 6, # 8 Exhibit 7, # 9 Exhibit 8, # 10 Text of Proposed Order Proposed Order)(Kramer Katz, Madelaine) (Entered: 06/07/2023)
06/21/2023	<u>27</u>	RESPONSE in Support re <u>25</u> MOTION for Summary Judgment filed by EREK L BARRON, Robert M. Califf, MERRICK B GARLAND, U.S. Food and Drug Administration.(Shelton, Alicia) (Entered: 06/21/2023)
01/29/2024	<u>28</u>	LETTER ORDER directing defendants to submit the file to the Court for in camera review by February 9, 2024. Signed by Judge Deborah L. Boardman on 1/29/2024. (ybs, Deputy Clerk) (Entered: 01/29/2024)
02/21/2024	<u>29</u>	MEMORANDUM OPINION. Signed by Judge Deborah L. Boardman on 2/21/2024. (ybs, Deputy Clerk) (Entered: 02/21/2024)
02/21/2024	<u>30</u>	ORDER granting in part and denying in part <u>25</u> Motion for Summary Judgment; denying <u>26</u> plaintiffs request for discovery. Signed by Judge Deborah L. Boardman on 2/21/2024. (ybs, Deputy Clerk) (Entered: 02/21/2024)
03/08/2024	<u>31</u>	NOTICE by U.S. Food and Drug Administration re <u>30</u> Order on Motion for Summary Judgment <i>Davis Declaration</i> (Shelton, Alicia) (Entered: 03/08/2024)
03/11/2024	32	PAPERLESS ORDER scheduling an on–the–record call regarding <u>31</u> for Thursday, April 18 at 10:00am. My chambers will circulate call–in information. Signed by Judge Deborah L. Boardman on 3/11/2024. (mm10s, Chambers) (Entered: 03/11/2024)
04/18/2024	<u>33</u>	Telephone Conference held on 4/18/2024 before Judge Deborah L. Boardman. (FTR – Gomez – 4A) (dg3s, Deputy Clerk) (Entered: 04/18/2024)
04/25/2024	<u>34</u>	Correspondence re: intent to file motion for summary judgment (Kramer Katz, Madelaine) (Entered: 04/25/2024)