UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

KYLE THOMAS ROZEMA,

Plaintiff,

v.

5:14-CV-0495
(GTS/DEP)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and U.S. FOOD AND DRUG ADMINISTRATION,

Defendants,

PHILIP MORRIS USA, INC.; LORILLARD TOBACCO CO.; R.J. REYNOLDS TOBACCO CO.; and SANTA FE NATURAL TOBACCO CO., INC.,

Intervenors-Defendants.

APPEARANCES: OF COUNSEL:

KYLE THOMAS ROZEMA
Plaintiff, *Pro Se*
340 East North Water Street, Apt. 3308
Chicago, IL 60611

HON. RICHARD S. HARTUNIAN
United States Attorney for the
Northern District of New York
Counsel for Defendants
100 South Clinton Street
Syracuse, NY 13261

WILLIAM F. LARKIN, ESQ.
Assistant United States Attorney

HARRIS BEACH LLP
Counsel for Intervenor-Defendant
Philip Morris USA, Inc.
726 Exchange Street, Suite 1000
Buffalo, NY 14210

RICHARD T. SULLIVAN, ESQ.

COVINGTON & BURLING LLP
Counsel for Intervenor-Defendant
Lorillard Tobacco Company
620 Eighth Avenue
New York, NY 10018

DOUGLAS S. CURRAN, ESQ.

KING & SPALDING LLP
Counsel for Intervenor-Defendants
R.J. Reynolds Tobacco Company
and Santa Fe Natural Tobacco
Company, Inc.
1700 Pennsylvania Ave, NW
Washington, DC 20006

MEREDITH MOSS, ESQ.

GLENN T. SUDDABY, Chief United States District Judge

DECISION and ORDER

Currently before the Court, in this action pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et. seq.*, filed by Kyle Thomas Rozema ("Plaintiff") against the United States Department of Health and Human Services ("HHS") and the United States Food and Drug Administration ("FDA"), are the following motions: (1) a motion for summary judgment filed by Defendants HHS and FDA (Dkt. No. 40); (2) a motion for summary judgment filed jointly by three of four Intervenor-Defendants, Philip Morris USA Inc. ("Philip Morris"), R.J. Reynolds Tobacco Company ("Reynolds"), and Santa Fe Natural Tobacco Company, Inc. ("Santa Fe") (Dkt. No. 41); (3) a motion for summary judgment filed by the fourth Intevenor-Defendant, Lorillard Tobacco Company ("Lorillard") (Dkt. No. 42); and (4) Plaintiff's cross-motion for summary judgment (Dkt. No. 45). For the reasons set forth below, Defendants' motions are granted, and Plaintiff's cross-motion is denied.

I. RELEVANT BACKGROUND

A. Introduction

This action arises from Plaintiff's challenge to the administrative denial of his FOIA request dated September 19, 2013, directed to the FDA, for information regarding the quantities of menthol contained in cigarettes "by brand and by quantity in each brand and subbrand from 2000 to 2010." (Dkt. No. 1, ¶ 6 [Plf.'s Compl.].) Generally, Plaintiff's Complaint alleges that HHS and FDA (collectively, "the Agency Defendants") improperly withheld the requested records and that Plaintiff has exhausted his administrative remedies. (*Id.*, ¶¶ 7-15.) On that basis, Plaintiff seeks an Order directing the Agency Defendants to disclose the requested records and an award of costs and attorney's fees regarding his request. (*Id.*)

After Plaintiff filed his Complaint in this action, Philip Morris, Reynolds, Santa Fe, and Lorillard moved (collectively, "Intervenors")[1] moved to intervene for the purpose of defending against the disclosure of the information Plaintiff seeks, which includes menthol quantities contained in products manufactured by those entities. (Dkt. Nos. 14, 23, 27.) Those motions were granted without opposition by Plaintiff or the Agency Defendants. (Dkt. Nos. 22, 28, 34.)[2]

B. Statutory Framework

Congress enacted the Family Smoking Prevention and Tobacco Control Act ("the Act"), 21 U.S.C. § 387 *et seq.*, to grant FDA the authority to regulate, among other things, "all cigarettes [and] cigarette tobacco[.]" 21 U.S.C. § 387a(b); *U.S. Smokeless Tobacco Mfg. Co.*

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[1] Reference in this Decision and Order to "Defendants," generally, refers to the Agency Defendants and Intervenors, collectively.

[2] Reynolds and Santa Fe, represented by the same counsel, jointly moved to intervene, and Plaintiff responded that he had no opposition to intervention by either entity. (Dkt. No.. 27, 33.) However, the Text Order granting the motion to intervene directed the Clerk of the Court to add only Reynolds as an Intervenor-Defendant in this action, and did not mention Santa Fe. (Dkt. No. 34 [Text Order, filed 8/12/2014].) The Clerk of the Court is directed to add Santa Fe Natural Tobacco Company, Inc., as an Intervenor-Defendant in this action.

LLC v. City of New York, 708 F.3d 428, 430 (2d Cir. 2013).[3] As part of the Act, Congress also directed FDA to establish a twelve-member Tobacco Products Scientific Advisory Committee ("TPSAC"), the duties of which include providing advice, information, and recommendations to FDA on safety issues related to menthol cigarettes. 21 U.S.C. §§ 387g(e), 387q(c). While the Act grants a broad scope of authority to FDA, Plaintiff's FOIA request implicates that portion of the Act's statutory and regulatory framework governing the submission of health-related information to FDA by tobacco product manufacturers ("TPMs").

More specifically, section 904 of the Act, 21 U.S.C. § 387d, requires TPMs to submit to FDA certain information concerning, among other things, the cigarettes that they manufacture. As is relevant here, first, TPMs are required to submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are . . . added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand." 21 U.S.C. § 387d(a)(1) ("Ingredient Listings"). Second, TPMs must submit, at FDA's request, documents and information related to research activities and scientific findings pertaining to, among other things, the health effects of tobacco products and their constituents. 21 U.S.C. § 387d(b)(1)-(3) ("Research Documents"). Third, and perhaps most importantly here, TPMs must submit listings of all constituents identified by FDA as harmful or potentially harmful ("HPHCs") in each tobacco product, "by brand and by quantity in each brand and subbrand." 21 U.S.C. § 387d(a)(3). FDA published a list of 93 HPHCs ("HPHC List") in

[3] Many of the statutory provisions at issue refer to the authority and duties of "the Secretary" of HHS relative to tobacco regulation. In that regard, and for the sake of clarity, the Court generally refers to "FDA" throughout this Decision and Order because the Secretary has delegated all authority under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, to the Commissioner of the FDA. Act of June 22, 2009, Pub. L. No. 111-31, 2009 U.S.C.C.A.N. 468 (123 Stat 1776) (2009).

2012, and menthol was not listed. 77 Fed. Reg. 20034, 20036-37 (Apr. 3, 2012).[4] FDA is required to "place on public display" the HPHC quantities reported by TPMs in a format that is "not misleading to a lay person" and "in a manner determined by" FDA. 21 § U.S.C. 387d(d)(1).[5] With limited exceptions not applicable here, any information that TPMs report to FDA pursuant to 21 U.S.C. § 387d, which also constitutes trade secret and/or commercial or financial information under FOIA Exemption 4, 5 U.S.C. § 552(b)(4), "shall be considered confidential and shall not be disclosed[.]" 21 U.S.C. 387f(c); *see also* 21 C.F.R. § 20.61(c) ("Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.").

C. Procedural History and Undisputed Material Facts

1. Plaintiff's Failure to File a Statement of Material Facts

As a preliminary matter, in his memorandum of law in opposition to the motions for summary judgment filed by Defendants and in support of his cross-motion for summary judgment, Plaintiff acknowledges that FDA "conducted an adequate search" in response to his FOIA request, but argues that it improperly withheld the responsive records that it located. (Dkt. No. 45 at 1 [Plf.'s Memo. of Law].) Plaintiff filed neither a response to Defendants' Statements of Material Facts nor a Statement of Material Facts in support of his cross-motion, as required by Local Rule 7.1(a)(3) of the Local Rules of Practice; indeed, in his memorandum of law, he

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[4] FDA's list of HPHCs is available on its website. http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm (last visited January 27, 2016).

[5] The statute required FDA to publish the list of HPHC quantities in tobacco products "[n]ot later than 3 years after June 22, 2009, and annually thereafter[.]" 21 U.S.C. § 387d(d)(1). FDA has not yet placed a listing of HPHC quantities on public display. (Dkt. No. 40, Attach. 2 at 3 n.3 [Agency Defs.' Memo. of Law].)

asserts that no factual dispute exists and expressly incorporates by reference both the "background" and "legal standard" portions of the memorandum of law filed by the Agency Defendants. (*Id.* at 1-2.)

Pursuant to Local Rule 7.1(a)(3), a party moving for summary judgment is required to submit a statement of material facts. N.D.N.Y. L.R. 7.1(a)(3). Moreover, a party opposing a motion for summary judgment is required to submit a statement of material facts, even where the opposing party intends to admit facts asserted by the moving party. N.D.N.Y. L.R. 7.1(a)(3) ("The non-movant's response shall mirror the movant's Statement of Material Facts by admitting and/or denying each of the movant's assertions in matching numbered paragraphs."). Upon an opposing party's failure to submit a statement of material facts, "[t]he Court shall deem admitted any properly supported facts set forth in" a moving party's statement of material facts. *Id.* [emphasis in original]. Plaintiff was reminded of his obligation to file a Rule 7.1 Response when the Agency Defendants and Philip Morris, Reynolds, and Santa Fe filed their respective motions for summary judgment. (Dkt. No. 40, Attach. 7 [Notification of the Consequences of Failing to Respond to a Summary Judgment Motion]; Dkt. No. 41, Attach. 18 [same].)

In this case, Plaintiff does not (and apparently did not intend to) dispute any of the factual assertions advanced in support of Defendants' motions for summary judgment, but rather disagrees with FDA's application of the statutory framework–particularly FOIA Exemptions 3 and 4–in denying his FOIA request. (*See, e.g.*, Dkt. No. 45 at 2 [acknowledging that "requiring public disclosure of the quantities of cigarette constituents imposes economical costs on tobacco product manufacturers to a significant, and perhaps incalculable, amount," but arguing that "Congress decided to increase public awareness of the harmful constituents in cigarettes anyway"]). Indeed, Plaintiff does not dispute the factual assertions advanced by Intervenors in

support of the proposition that menthol quantities in cigarettes constitute trade secrets and/or confidential commercial information (and thus, ostensibly, would fall within the ambit of FOIA Exemptions 3 and/or 4). As more fully discussed below, the crux of Plaintiff's argument appears to be that "FOIA Exemptions 3 and 4 are not binding authority in this case" because they are entirely inapplicable to the Act. (*Id.*) To the extent that discussion of the factual background is necessary to illuminate the issue of whether Plaintiff's FOIA request was properly denied under applicable legal standards, that factual background is therefore drawn from the uncontradicted, record-supported facts set forth in the Rule 7.1 Statements filed by Defendants.

2. Undisputed Material Facts

a. Role of Menthol in Intervenors' Businesses

Lorillard manufactures Newport cigarettes, the top-selling menthol cigarette in the United States, and each of the Intervenors manufacture cigarettes that contain menthol. (Dkt. No. 42, Attach. 2, ¶ 2 [Lorillard's Rule 7.1 Statement]; Dkt. No. 41, Attach. 11, ¶ 33 [Rule 7.1 Statement for Philip Morris, Reynolds, and Santa Fe].) Menthol cigarettes currently account for 33% of all cigarette sales. (Dkt. No. 41, Attach. 11, ¶ 66.)

Menthol is a key component of a cigarette's "proprietary recipe" and brand identity, and small variations in menthol quantities may substantially alter a cigarette's flavor profile and aroma. (Dkt. No. 41, Attach. 11, ¶¶ 41-43; Dkt. No. 42, Attach. 2, ¶¶ 14-17, 26.) Intervenors' formulae for the manufacture of cigarettes represent many years of, and significant financial expenditure in, research and development. (Dkt. No. 41, Attach. 11, ¶¶ 48-51; Dkt. No. 42, Attach. 2, ¶¶ 25-26.) Dissemination of menthol quantities in a TPM's cigarettes creates numerous risks, including reducing the TPM's share in a fiercely competitive market, allowing

other entities to unfairly replicate a product without undertaking the substantial time and financial investment needed to craft the product's recipe, and giving counterfeiters the opportunity to employ that information in the illicit manufacture of cigarettes. (Dkt. No. 41, Attach. 11, ¶¶ 59-65, 74-79; Dkt. No. 42, Attach. 2, ¶¶ 36-51; Dkt. No. 41, Attach. 2, ¶¶ 31-37 [Swauger Decl.]; Dkt. No. 41, Attach. 10, ¶¶ 19-26 [Jupe Decl.]; Dkt. No. 42, Attach. 3, ¶¶ 28-30 [Wilcox Decl.].) In short, the ingredient information for Intervenors' products, including menthol quantities, carry enormous financial value. (Dkt. No. 41, Attach. 11, ¶ 61; Dkt. No. 42, Attach. 2, ¶¶ 17, 25.)

In view of these concerns, Intervenors consider their product formulae, including menthol quantities, proprietary trade secrets, and closely guard this information against dissemination. Philip Morris, Reynolds, and Santa Fe have implemented "extensive" written security and confidentiality policies, segregate ingredient and formula information from other records, and permit electronic access to that information only to specific employees after proper authentication. (Dkt. No. 41, Attach. 11, ¶¶ 53-56; Dkt. No. 41, Attach. 2, ¶¶ 16-30 [Swauger Decl.]; Dkt. No. 41, Attach. 10, ¶¶ 5-13 [Jupe Decl.].) Lorillard stores ingredient information "on a dedicated and secure computer server" accessible to only a limited number of authorized employees who have agreed to maintain the confidentiality of that information. (Dkt. No. 42, Attach. 2, ¶¶ 30-34; Dkt. No. 42, Attach. 3, ¶¶ 19-22 [Wilcox Decl.].)

b. Plaintiff's FOIA Request and Administrative Appeal

FDA is an agency within HHS. The Secretary of HHS has redelegated all functions invested in him to the Commissioner of Food and Drugs. (Dkt. No. 40, Attach. 5, at ¶ 1 [Agency Defs.' Rule 7.1 Statement].) The Center for Tobacco Products ("CTP"), established as an agency center within FDA, possesses the authority to regulate tobacco products. (*Id.* at ¶ 2; Dkt. No. 40,

Attach. 4, ¶ 2 [German Decl.].) 21 U.S.C. § 387a(e). Before April 2014, CTP's Office of the Center Director ("OCD") handled FOIA requests seeking documents in CTP's possession; after a reorganization in or around April 2014, that task was assumed by CTP's Office of Health Communication and Education ("OHCE") (collectively, "CTP FOIA"). (Dkt. No. 4, Attach. 5, at ¶ 3 & n.1.)

On September 19, 2013, Plaintiff electronically submitted to FDA's Division of Freedom of Information ("DFOI") a letter requesting certain records pursuant to FOIA. (*Id.* at ¶ 2; Dkt. No. 40, Attach. 3 ["Attachment 1" to Kotler Decl. (Plf.'s FOIA Request)].) In his request, Plaintiff described the records he sought as follows:

> I have been trying to locate the published list made public in April 2012 in regards to section 904(b) of the 2009 Family Smoking Prevention and Tobacco Control Act, topics 11 and 12 – the quantities of menthol in each cigarette by brand/sub-brand for all cigarettes from 2000 to 2010 that tobacco manufactures [*sic*] were supposed to have made by December 22, 2009. . . . I am requesting each brand/subbrand from 2000 to 2010[.]

(Dkt. No. 40, Attach. 3 ["Attachment 1" to Kotler Decl. (Plaintiff's FOIA Request)].) DFOI forwarded Plaintiff's request to CTP. (Dkt. No. 40, Attach. 5, ¶ 4.) Jennifer J. German, a regulatory policy analyst in CTP's OHCE, reviewed Plaintiff's FOIA request to determine which (if any) offices within CTP may have responsive records. (Dkt. No. 40, Attach. 4 [German Decl., ¶ 8].) Based upon that review, German forwarded Plaintiff's FOIA request to CTP's Office of Science ("OS"), and requested that OS perform a search for responsive documents. (*Id.*)

Upon reviewing Plaintiff's FOIA request, OS informed German that Plaintiff was requesting information submitted by TPMs to FDA pursuant to Section 904(a)(1) of the FDCA,

21 U.S.C. § 387d(a)(1) (that is, Ingredient Listings).[6] (Dkt. No. 40, Attach. 5, ¶ 5; Dkt. No. 40, Attach. 4, ¶ 9.) OS advised German that Ingredient Listing information should not be disclosed because it constituted confidential commercial information. (Dkt. No. 40, Attach. 5, ¶ 5; Dkt. No. 40, Attach. 4, ¶ 9.)

Ultimately, DFOI denied Plaintiff's FOIA request, in its entirety, on the ground that his request sought trade secret and confidential commercial information exempt from disclosure. (Dkt. No. 40, Attach. 5, ¶ 11; Dkt. No. 40, Attach. 3, at 12-13 ["Attachment 3" to Kotler Decl. (FDA's Written Denial of FOIA Request, dated October 18, 2013)].) In support of its determination, DFOI cited, *inter alia*, FOIA Exemption 4, 5 U.S.C. § 552(b)(4); 45 C.F.R. § 5.65;[7] and C.F.R. § 20.61(c). (*Id.*)

By letter dated October 29, 2013, Plaintiff administratively appealed the denial of his FOIA request to HHS. (Dkt. No. 40, Attach. 3 at 17-21 ["Attachment 4" to Kotler Decl. (Plaintiff's FOIA Appeal)].) In his appeal letter, Plaintiff argued that menthol is, or at least "should be considered," an HPHC, and, therefore, menthol quantities must be publicly disseminated. (*Id.* at 18-19.) Moreover, citing an FDA document titled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes,"

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[6] Plaintiff's FOIA request references 21 U.S.C. § 387d(b) (governing the submission to FDA of Research Documents); and, according to the Agency Defendants, OS interpreted Plaintiff's request as seeking Ingredient Lists under § 387d(a)(1). However, in their respective motions, the parties do not dispute (and Plaintiff's FOIA request otherwise makes clear) that Plaintiff seeks menthol quantities on the basis that menthol is an HPHC of tobacco products, and that menthol quantities contained in cigarettes must therefore be submitted to FDA by manufacturers and, in turn, released to the public by FDA. 21 U.S.C. § 387d(a)(3), (d)(1), (e).

[7] This regulation, which implements FOIA Exemption 4, provides, in part, that "[w]e will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential," and provides definitions of those terms. 45 C.F.R. § 5.65.

Plaintiff argued that FDA itself viewed menthol as an HPHC.[8] (*Id.* at 18-19.)

In a letter decision dated March 11, 2014, HHS concluded that FDA properly withheld the records Plaintiff requested under FOIA Exemptions 3 and 4. (Dkt. No. 40, Attach. 3 at 23-25 ["Attachment 5" to Kotler Decl. (Final Response to Appeal)].) HHS reasoned that menthol quantities in cigarettes–contained in Ingredient Listings disclosed to FDA by TPMs–were "clearly trade secret" and confidential commercial information under the statutory and regulatory framework, and that disclosure of any information obtained under the authority of 21 U.S.C. § 387d was prohibited. (*Id.* at 24.) Moreover, HHS noted that, because FDA did not include menthol on its list of HPHCs, menthol was not captured in the requirement that FDA publish a list of HPHCs. *Id.* at 23.

c. Agency Action Following Commencement of this Case

After learning that Plaintiff had filed his Complaint in the present action, CTP FOIA conferred with OS again regarding "possible responsive documents." (Dkt. No. 40, Attach. 4, ¶ 13 [German Decl.].) This renewed review of Plaintiff's request resulted in three findings. First, OS advised CTP FOIA that FDA had no "HPHC Reports" that contained information on menthol quantities because menthol is not on the HPHC List about which TPMs must provide data to FDA. (*Id.*, ¶ 13.)

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[8] In this 153-page document, FDA undertook a "thorough review of the available science concerning menthol cigarettes" by weighing studies "for the impact of the use of menthol in cigarettes on public health." U.S. Food and Drug Administration, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* (available at http://www.fda.gov/downloads/UCM361598.pdf [last visited Jan. 26, 2016]). The executive summary notes that the document "does not constitute a decision about what regulatory action, if any, FDA might take with respect to menthol in cigarettes." (*Id.* at 7.) According to a subsequent Reference Addendum, this scientific report was submitted for peer review in August 2011. U.S. Food and Drug Administration, *Reference Addendum: "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes*" (available at http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewof ScientificInformationandAssessments/UCM362600.pdf [last visited Jan. 26, 2016]).

Second, OS noted that information regarding menthol quantities appeared in "other CTP documents," specifically, in the Ingredient Listings that TPMs submit to FDA as required by 21 U.S.C. § 387d(a)(1). (*Id.*, ¶ 14.) OS executed a search of CTP's Inventory Tracking Recording and Control database, which holds and categorizes TPMs' submissions, for documents responsive to Plaintiff's request. (*Id.*) That search revealed 34 Ingredient Listings that included tobacco products' respective menthol quantities. (*Id.*)[9]

Third, German located "additional documents" responsive to Plaintiff's FOIA request. (*Id.*, ¶ 15.) In a letter dated May 26, 2010, pursuant to Section 904(b) of the FDCA, 21 U.S.C. § 387d(b), CTP requested that TPMs submit Research Documents on numerous topics related to menthol cigarettes. (*Id.*; Dkt. No. 40, Attach. 4 at 13-15 ["Attachment 1" to German Decl. (Menthol Request Letter)].) CTP also requested, "beyond the section 904(b) request," that each recipient of the letter provide information related to a list of numbered topics as "additional background information." (Dkt. No. 40, Attach. 4 at 14). Among these requests for additional information, Topic Number 11 requested "[q]uantities of menthol and nicotine in the cigarette by brand/subbrand and by year between 2000 and 2010." (*Id.*) CTP advised recipients that, "[c]onsistent with applicable statutes and regulations, the confidentiality of trade secret and confidential commercial information submitted to FDA pursuant to this request will be preserved." (*Id.*) A "subset" of the TPMs that received the Menthol Request Letter voluntarily submitted data on menthol quantities ("Topic 11 Responses"). (Dkt. No. 40, Attach. 4, ¶ 15

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[9] In June 2010, Reynolds, Santa Fe, and Philip Morris submitted Ingredient Listings, including menthol quantities used in manufacturing cigarettes by brand and subbrand. (Dkt. No. 41, Attach. 11, ¶¶ 11-13 [Rule 7.1 Statement for Philip Morris, Reynolds, and Santa Fe]; Dkt. No. 41, Attach. 2, ¶¶ 10-15 [Swauger Decl.].)

[German Decl.].) FDA compiled a "subset" of those responses into spreadsheets that summarized the data on menthol quantities found in cigarettes during that time frame ("Topic 11 Spreadsheets"). (*Id.*) Both the Topic 11 Responses and Topic 11 Spreadsheets contained information responsive to Plaintiff's FOIA request.[10] (*Id.*)

Ultimately, CTP FOIA concluded that the Topic 11 documents were also exempt from disclosure under FOIA Exemption 4. (*Id.*) However, in response to a letter from CTP concerning the possible need to disclose Topic 11 documents to Plaintiff, Lorillard advised CTP that it withdrew any objection to disclosure of "approximately fifteen (15) pages of Lorillard's Topic 11 Response" because that information had previously been publically disclosed. (*Id.*, ¶ 18.) As a result, German produced those 15 pages to Plaintiff. (*Id.*)

Familiarity with the remaining material (and, again, undisputed) facts of this action is assumed in this Decision and Order, which is intended primarily for review by the parties.

C. Parties' Briefings on the Pending Motions

1. Defendants' Motions for Summary Judgment

Generally, in support of their motion for summary judgment, the Agency Defendants assert four arguments: (1) "HPHC Reports" for menthol do not exist because menthol is not classified as an HPHC, and thus, TPMs are not required to submit the quantities of menthol in their products to FDA under the HPHC reporting requirement; (2) FDA conducted an adequate search for responsive records; (3) FDA properly withheld all responsive information pursuant to FOIA Exemption 4 because (a) the quantities of menthol in TPMs' products are trade secrets, and

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[10] Philip Morris submitted a Topic 11 Response regarding menthol quantities on an "encrypted computer hard drive." (Dkt. No. 41, Attach. 11, ¶ 19.) Reynolds and Santa Fe responded to the Menthol Request Letter by providing certain "additional background information," but did not submit menthol quantity information. (*Id.*, ¶ 23.)

TPMs (including Intervenors) consider such information to be trade secrets, and (b) the requested information also constituted confidential commercial information; and (4) FDA properly withheld the Ingredient Listings (i.e., information submitted to FDA as required by 21 U.S.C. § 387d[a][1]) pursuant to FOIA Exemption 3 because (a) 21 U.S.C. § 387f(c) and 21 U.S.C. § 331(j) each qualify as withholding statutes, and (b) the Ingredient Listings fall within the scope of those statutes for the same reasons that they meet the criteria of FOIA Exemption 4 (that is, the Ingredient Listings are trade secret and confidential commercial information). (Dkt. No. 40, Attach. 2 at 7-21 [Agency Defs.' Memo. of Law].)

Generally, in support of their motions for summary judgment, Philip Morris, Reynolds, and Santa Fe assert three arguments: (1) the quantities of menthol that these entities used to manufacture cigarettes constitute both trade secrets and confidential commercial information under FOIA Exemption 4; (2) any information reflecting menthol quantities that Philip Morris submitted in its Topic 11 Responses in response to FDA's Menthol Request Letter is exempt from disclosure under FOIA Exemption 4 because that information (a) constitutes confidential commercial information, and (b) was voluntarily produced and not otherwise made public;[11] and (3) menthol is not on FDA's list of HPHCs, and Plaintiff is therefore not entitled to information on menthol quantities in tobacco products under 21 U.S.C. § 387d(e). (Dkt. No. 41, Attach. 1 at 9-24 [Memo. of Law for Philip Morris, Reynolds, and Santa Fe].)

Generally, in support of its motion for summary judgment, Lorillard argues that the type and quantity of menthol in its cigarettes constitute both trade secrets and confidential commercial information, and FOIA Exemption 4 therefore applies. (Dkt. No. 42, Attach. 1 at 2-

[11] This argument applies only to Philip Morris, inasmuch as Reynolds and Santa Fe have no responsive documents in this category. (Dkt. No. 41, Attach. 1 at 19 n.7.)

7 [Lorillard's Memo. of Law].)[12]

2. Plaintiff's Opposition to Defendants' Motions for Summary Judgment and His Cross-Motion for Summary Judgment

Generally, construed liberally, in response to Defendants' motions for summary judgment and in support of his cross-motion for summary judgment, Plaintiff asserts seven arguments: (1) even if the information he seeks constitutes trade secrets or confidential commercial information for purposes of FOIA Exemption 4, the plain language of 21 U.S.C. § 387d(d)(1) "makes these exemptions inapplicable"; (2) TPSAC, rather than FDA, has the authority to determine whether menthol is an HPHC and, because TPSAC has stated its position that menthol is harmful or potentially harmful, FDA must disclose the requested information pursuant to 21 U.S.C. § 387d(a)(3) and (d)(1); (3) even if Congress did not delegate to TPSAC the responsibility to determine HPHCs, FDA itself has "accepted the determination that menthol is harmful or potentially harmful" in other publications, and its failure to release menthol quantity data to Plaintiff constitutes an "irregularity" that this Court must correct; (4) regardless of either FDA's position or TPSAC's position on the harmfulness of menthol, Congress has "decided for itself" that menthol is an HPHC because it directed FDA to study the harmfulness of menthol, and FDA therefore "has a duty to release the records" under section 904(d)(1) of the Act; (5) whether menthol was deemed harmful or potentially harmful *at the time* cigarette manufacturers submitted menthol quantity data is irrelevant, because menthol is now recognized as at least potentially harmful; (6) the statutory provision pursuant to which data regarding menthol quantities was submitted to FDA (that is, 21 § U.S.C. 387d[a][1] or [a][3]) is irrelevant in light

[12] Lorillard also incorporates by reference the argument advanced by the Agency Defendants that menthol quantities in cigarettes are exempt from disclosure pursuant to FOIA Exemption 3. (Dkt. No. 42, Attach. 1 at 1 n.1.)

of menthol's current status as an HPHC; and (7) Intervenors' responses to FDA's Menthol Request Letter for Research Documents pursuant to 21 U.S.C. § 387d(b) (that is, the portions responding to the nonvoluntary topics of the request, aside from Topic 11) must be disclosed because Congress intended those materials to be made public as demonstrated by 21 U.S.C. § 387(6) and § 387o(b)(2). (Dkt. No. 45 at 2-23 [Plf.'s Memo. of Law].)

3. Defendants' Replies

Generally, in their reply, the Agency Defendants assert seven arguments: (1) FDA's HPHC List does not include menthol, and the determination that menthol should be included in FDA's HPHC List can be accomplished only by agency notice-and-comment rulemaking procedures pursuant to 21 U.S.C. § 387g(c)(1)-(3); (2) TPSAC is an advisory committee to FDA and has no authority to declare HPHCs; (3) FDA draft guidance and report documents do not bind FDA regarding its promulgation of the HPHC List; (4) Congress has not unilaterally determined that menthol is an HPHC for purposes of 21 U.S.C. § 387d merely by directing TPSAC to study menthol; (5) FDA properly withheld records responsive to Plaintiff's FOIA request pursuant to FOIA Exemptions 3 and 4; (6) the Act does not "preclude" the application of FOIA Exemptions 3 and 4 because (a) the statutory provisions can logically coexist, and (b) 21 U.S.C. § 387f(c) unequivocally protects from disclosure any information TPMs submit to FDA pursuant to the Act's tobacco provisions where that information is protected under FOIA Exemption 4; and (7) 21 U.S.C. § 387(6) and § 387o(b)(2) are general provisions that impose no substantive requirements that any information be disclosed. (Dkt. No. 48 at 2-13 [Agency Defs.' Reply Memo. of Law].)

Generally, in their joint reply, Intervenors assert four arguments: (1) Plaintiff does not dispute that the information that he requests constitutes trade secrets and confidential commercial information for purposes of FOIA Exemptions 3 and 4; (2) FDA's HPHC List does not include menthol, and thus, 21 U.S.C. § 387d does not mandate disclosure of menthol quantities in cigarettes; (3) any argument that menthol is an HPHC (or should be so listed) should have been raised in the context of the regulation's notice-and-comment period rather than in a FOIA action; and (4) even if Plaintiff could properly litigate in this action FDA's determination not to designate menthol as an HPHC, he has not established that the FDA's determination was arbitrary and capricious under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). (Dkt. No 49 at 3-11 [Intervenors' Reply Memo. of Law].)

II. RELEVANT LEGAL STANDARDS

A. Legal Standard Governing Motions for Summary Judgment, Generally

Under Fed. R. Civ. P. 56, summary judgment is warranted if "the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute of fact is "genuine" if "the [record] evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). As a result, "[c]onclusory allegations, conjecture and speculation . . . are insufficient to create a genuine issue of fact." *Kerzer v. Kingly Mfg.*, 156 F.3d 396, 400 (2d Cir. 1998) (citation omitted); *see also* Fed. R. Civ. P. 56(e)(2). As the Supreme Court has famously explained, "[the non-moving party] must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). As for the materiality requirement, a dispute

of fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson*, 477 U.S. at 248. "Factual disputes that are irrelevant or unnecessary will not be counted." *Id.*

In determining whether a genuine issue of material fact exists, the Court must resolve all ambiguities and draw all reasonable inferences against the moving party. *Anderson*, 477 U.S. at 255. In addition, "[the moving party] bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the . . . [record] which it believes demonstrate[s] the absence of any genuine issue of material fact." *Celotex v. Catrett*, 477 U.S. 317, 323 (1986); *see also* Fed. R. Civ. P. 56(c), (e). However, when the moving party has met this initial burden of establishing the absence of any genuine issue of material fact, the nonmoving party must come forward with specific facts showing a genuine dispute of material fact for trial. Fed. R. Civ. P. 56(c), (e). Where the non-movant fails to deny the factual assertions contained in the movant's Rule 7.1 Statement of Material Facts in matching numbered paragraphs supported by a citation to admissible record evidence (as required by Local Rule 7.1[a][3] of the Court's Local Rules of Practice), the court may not rely solely on the movant's Rule 7.1 Statement; rather, the court must be satisfied that the citations to evidence in the record support the movant's assertions. *See Giannullo v. City of N.Y.*, 322 F.3d 139, 143 n.5 (2d Cir. 2003) (holding that not verifying in the record the assertions in the motion for summary judgment "would derogate the truth-finding functions of the judicial process by substituting convenience for facts").

Finally, when a non-movant fails to oppose a legal argument asserted by a movant, the movant's burden with regard to that argument is lightened, such that, in order to succeed on that

argument, the movant need only show that the argument possesses facial merit, which has appropriately been characterized as a "modest" burden. *See* N.D.N.Y. L.R. 7.1(b)(3) ("Where a properly filed motion is unopposed and the Court determined that the moving party has met its burden to demonstrate entitlement to the relief requested therein . . . ."); *Rusyniak v. Gensini*, 07-CV-0279, 2009 WL 3672105, at *1, n.1 (N.D.N.Y. Oct. 30, 2009) (Suddaby, J.) (collecting cases); *Este-Green v. Astrue*, 09-CV-0722, 2009 WL 2473509, at *2 & n.3 (N.D.N.Y. Aug. 7, 2009) (Suddaby, J.) (collecting cases).

B. Summary Judgment Motions in FOIA Actions

As a preliminary matter, "FOIA was enacted in order to 'promote honest and open government and to assure the existence of an informed citizenry [in order] to hold the governors accountable to the governed.'" *Nat'l Council of La Raza v. Dep't of Justice*, 411 F.3d 350, 356 (2d Cir. 2005) (quoting *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 478 [2d Cir. 1999]). "FOIA strongly favors a policy of disclosure, and requires the government to disclose its records unless its documents fall within one of the specific, enumerated exemptions set forth in the Act." *Nat'l Council of La Raza*, 411 F.3d at 355 (internal citation omitted); *accord*, 5 U.S.C. § 552(a)(3), (b)(1)-(9). The statutory exemptions "have been consistently given a narrow compass[.]" *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (citation and internal quotation marks omitted).

"Summary judgment is the procedural vehicle by which most FOIA actions are resolved." *Ivey v. U.S. Dept. lf Justice Executive Office for U.S. Atty.*, 13-CV-0917, 2015 WL 507219, at *3 (N.D.N.Y. Feb. 6, 2015) (D'Agostino, J.) (citation and internal quotation marks omitted). "In order to prevail on a motion for summary judgment in a FOIA case, the defending agency has

the burden of showing that its search was adequate and that any withheld documents fall within an exemption to the FOIA." *Carney v. U.S. Dept. of Justice*, 19 F.3d 807, 812 (2d Cir. 1994). "Affidavits or declarations supplying facts indicating that the agency has conducted a thorough search and giving reasonably detailed explanations why any withheld documents fall within an exemption are sufficient to sustain the agency's burden." *Carney*, 19 F.3d at 812 (footnote omitted); *accord*, *Associated Press v. U.S. Dep't of Justice*, 549 F.3d 62, 65 (2d Cir. 2008); *Doolittle v. U.S. Dep't of Justice, Drug Enf't Agency*, 142 F. Supp. 2d 281, 284 (N.D.N.Y. 2001) (Hurd, J.). Affidavits submitted by an agency are entitled to a presumption that they were made in good faith. *Carney*, 19 F.3d at 812; *accord*, *Schwarz v. Dep't of Justice*, 417 F. App'x 102, 102 (2d Cir. 2011) (summary order). However, "conclusory affidavits that merely recite statutory standards, or are overly vague or sweeping will not, standing alone, carry the government's burden[.]" *Larson v. Dep't of State*, 565 F.3d 857, 864 (D.C. Cir. 2009). If the agency's submissions are facially adequate, summary judgment is appropriate "unless the plaintiff can make a showing of bad faith on the part of the agency or present evidence that the exemptions claimed by the agency should not apply." *Ivey*, 2015 WL 507219, at *3; *accord*, *Carney*, 19 F.3d at 812.

C. Exemptions from Disclosure Relevant to the Plaintiff's FOIA Request

In denying Plaintiff's FOIA request, the Agency Defendants invoked, *inter alia*, FOIA Exemptions 3 and 4. Because of the specific statutes at issue in this case, the applicability of the FOIA Exemptions overlap; whether FOIA Exemption 3 applies is dependent upon whether FOIA Exemption 4 applies.

1. FOIA Exemption 4

FOIA Exemption 4 "allows a federal agency . . . to refuse disclosure of 'trade secrets and commercial or financial information obtained from a person and privileged or confidential.'" *Bloomberg, L.P. v. Bd. of Governors of the Fed. Reserve Sys.*, 601 F.3d 143, 147 (2d Cir. 2010) (quoting 5 U.S.C. § 552[b][4]). This exemption applies when a three-part test is satisfied: "(1) [t]he information for which exemption is sought must be a trade secret or commercial or financial in character; (2) it must be obtained from a person; and (3) it must be privileged or confidential." *Bloomberg, L.P.*, 601 F.3d at 147 (quoting *Nadler v. FDIC*, 92 F.3d 93, 95 [2d Cir. 1996]) [emphasis removed].

For purposes of the first prong, commercial means "pertaining or relating to or dealing with commerce." *Am. Airlines, Inc. v. Nat'l Mediation Bd.*, 588 F.2d 863, 870 (2d Cir. 1978); *accord, e.g., New Hampshire Right to Life v. U.S. Dep't of Health and Human Servs.*, 778 F.3d 43, 49 (1st Cir. 2015) ("The FOIA does not define the term 'commercial,' so courts have given the term its ordinary meaning."); *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F2d 1280, 1290 (D.C. Cir. 1983); *New York Pub. Interest Research Grp. v. U.S. E.P.A.*, 249 F. Supp. 2d 327, 334 (S.D.N.Y. 2003) (concluding that certain analyses were not "commercial" because defendants did not establish that "the information has any intrinsic commercial value, that disclosure would jeopardize . . . commercial interests or reveal information about . . . ongoing operations, or that [the information was] generated . . . for a purpose other than advocating a policy to a government agency.").

"Trade secret" encompasses "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities

and that can be said to be the end product of either innovation or substantial effort." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1288 (footnote omitted); *accord, United Techn. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 563 n.9 (D.C. Cir. 2010); *Herrick v. Garvey*, 298 F.3d 1184, 1190 (10th Cir. 2002).[13]

For purposes of the second prong, a "person" includes "an individual, partnership, corporation, association, or public or private organization other than an agency." 5 U.S.C. § 551(2).

With regard to the third prong, information is confidential "if its disclosure would have the effect of either: '(1) of impairing the government's ability to obtain information–necessary information–in the future, or (2) of causing substantial harm to the competitive position of the person from whom the information was obtained.'" *Inner City Press/Comty. on the Move v. Bd. of Governors of Fed. Reserve Sys.*, 463 F.3d 239, 244 (2d Cir. 2006) (quoting *Cont'l Stock Transfer & Trust Co. v. SEC*, 566 F.2d 373, 375 [2d Cir. 1977]); *accord, Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). If submission to the Government is mandatory, however, "there is presumably no danger that public disclosure will impair the ability of the Government to obtain th[e] information in the future." *Inner City Press/Comty. on the Move*, 463 F.3d at 245 (citation, internal quotation marks, and footnote omitted).[14]

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[13] FDA regulations define "trade secret" in the same manner. 21 C.F.R. § 20.61(a).

[14] The Second Circuit has noted that the District of Columbia Circuit no longer applies the "impairment" or "substantial competitive harm" prong to information that is "voluntarily provided to the government." *Inner City Press/Comty. on the Move*, 463 F.3d at 245 n.6. Instead, information that is voluntarily submitted may be withheld pursuant to FOIA Exemption 4 if it "would customarily not be released to the public by the person from whom it was obtained." *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878-79 (D.C. Cir. 1992) (en banc). The Second Circuit declined to adopt that test in *Inner City Press/Comty. on the Move* because the parties did not argue for its adoption and the district court had not relied upon it. 463 F.3d at 245 n.6.

2. FOIA Exemption 3

"FOIA Exemption 3 applies to records 'specifically exempted from disclosure by statute,' provided that the statute 'requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue.'" *Wilner v. Nat'l Sec. Agency*, 592 F.3d 60, 71 (2d Cir. 2009) (quoting 5 U.S.C. § 552[b][3]). Two threshold criteria must be satisfied to warrant application of FOIA Exemption 3: "(1) the statute invoked qualifies as an exemption 3 withholding statute, and (2) the materials withheld fall within that statute's scope." *A. Michael's Piano, Inc. v. F.T.C.*, 18 F.3d 138, 143 (2d Cir. 1994); *accord, CIA v. Sims*, 471 U.S. 159, 167 (1985); *Wilner*, 592 F.3d at 72. "To determine whether [a] statute is a withholding statute, the court must decide whether it satisfies the threshold requirement that it specifically exempt matters from disclosure." *Long v. U.S. Dep't of Justice*, 778 F. Supp. 2d 222, 234 (N.D.N.Y. 2011) (Mordue, C.J.) (internal quotation marks omitted). "[I]n construing withholding statutes," the Second Circuit "look[s] to the plain language of the statute and its legislative history, in order to determine legislative purpose." *A. Michael's Piano*, 18 F.3d at 144; *accord, Sims*, 471 U.S. at 168-73.

The Agency Defendants invoked two statutes as withholding statutes in this case. First, section 906 of the Act, 21 U.S.C. § 387f, titled "General provisions respecting control of tobacco products," provides, in part, as follows:

> (c) Limited confidentiality of information
>
> Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 387c, 387d, 387g, 387h, 387i, 387j, 387k, or 374 of this title, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of Title 5 by reason of subsection (b)(4) of that section [codifying FOIA Exemption 4] shall be

> considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this subchapter, or when relevant in any proceeding under this subchapter.

21 U.S.C. § 387f(c).

Second, section 301(j) of the Act, 21 U.S.C. § 331(j), prohibits, with certain exceptions, "[t]he using by any person to his own advantage, or revealing . . . any information acquired under the authority of," *inter alia*, 21 U.S.C. § 387d, "concerning any method or process which as a trade secret is entitled to protection[.]"

III. ANALYSIS

A. Whether FDA's Search for Documents Was Adequate

After carefully considering the matter, the Court answers this question in the affirmative for the reasons stated in the Agency Defendants' memorandum of law. (Dkt. No. 40, Attach. 2, at 8-11 [Agency Defs.' Memo. of Law].)

To those reasons, the Court would add only that Plaintiff concedes that FDA's search for documents responsive to his FOIA request was adequate. (Dkt. No. 45 at 2 [Plf.'s Memo. of Law].) The record demonstrates that DFOI acted appropriately in routing Plaintiff's FOIA request to OS, the CTP office most likely to possess documents pertaining to menthol quantities. (Dkt. No. 40, Attach. 4, ¶¶ 8, 13-18 [German Decl.].)

B. Whether Menthol Is an HPHC for Purposes of 21 U.S.C. § 387d

After carefully considering the matter, the Court answers this question in the negative for the reasons stated in Defendants' reply memoranda of law. (Dkt. No. 48 at 3-7 [Agency Defs.' Reply Memo. of Law]; Dkt. No. 49 at 5-11 [Intervenors' Reply Memo. of Law].) To those reasons, the Court adds only one point.

The statutory framework makes clear that "the Secretary" of HHS (through which the FDA acts) is empowered, in accordance with applicable rulemaking procedures, to identify those constituents in tobacco products that qualify as HPHCs. *See, e.g.*, 21 U.S.C. § 387g(a)(3)(B)(ii) (pronouncing that parties may object to, and provide evidence regarding, the Secretary's determination that a tobacco product constituent should be reduced or eliminated because "the Secretary has found that the . . . constituent . . . is or may be harmful"); 21 U.S.C. § 387g(c)(1) ("The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.") FDA was tasked with establishing a list of HPHCs in each tobacco product "by brand and by quantity in each brand and subbrand," and placing the list on public display "in a manner determined by" FDA. 21 U.S.C. § 387d(d)(2), (e). Pursuant to its authority, FDA has not identified menthol (as of the date of this Decision and Order) as an HPHC.

C. Whether the Act Entirely Precludes the Application of the FOIA Exemptions

After carefully considering the matter, the Court answers this question in the negative for the reasons stated in Defendants' reply memoranda of law. (Dkt. No. 48 at 8-13 [Agency Defs.' Reply Memo. of Law]; Dkt. No. 49 at 5-7, 11-12 n.11 [Intervenors' Reply Memo. of Law].)[15]

[15] The Court emphasizes that, as Defendants argue, the plain language of 21 U.S.C. § 387f(c), which precludes disclosure of information that FDA obtains pursuant to § 387d, expressly incorporates the protection of trade secrets under FOIA Exemption 4. In short, regardless of its policy imperatives and the mechanisms codified to accomplish those imperatives, the Act contains a nondisclosure provision applicable to a specific class of information. This fact alone undercuts Plaintiff's unsupported argument that Congress intended tobacco-related information obtained by FDA under § 387d to escape the reach of any withholding statute or exemption from FOIA. To the extent that Plaintiff may be understood to argue that tension exists between FDA's duty to publish HPHC quantities by product brand and subbrand, on the one hand, and FOIA's exemption for trade secrets, on the other, that tension simply does not exist in this case because menthol is not an HPHC as defined by FDA.

D. Whether the Responsive Documents Identified by FDA Were Properly Withheld Pursuant FOIA Exemption 4

After carefully considering the matter, the Court answers this question in the affirmative for substantially all of the reasons stated in Defendants' memoranda of law and reply memoranda of law. (Dkt. No. 40, Attach. 2, at 11-19 [Agency Defs.' Memo. of Law]; Dkt. No. 48 at 8 [Agency Defs.' Reply Memo. of Law]; Dkt. No. 41, Attach. 1, at 9-19 [Memo. of Law for Philip Morris, Reynolds, and Santa Fe]; Dkt. No. 42, Attach. 1, at 2-7 [Lorillard's Memo. of Law]; Dkt. No. 49 at 3-5 [Intervenors' Reply Memo. of Law].) To those reasons, the Court adds only two points.

First, as noted above in Part I.C.1 of this Decision and Order, Plaintiff did not file a statement of material facts in opposition to Defendants' motions for summary judgment or in support of his cross-motion for summary judgment. Plaintiff has therefore not refuted the material facts advanced by Defendants in support of their arguments that FOIA Exemption 4 applies (that is, that menthol quantities constitute trade secrets and confidential commercial information and thus should not be disclosed to the public). Moreover, based upon its review of the records submitted on Defendants' motions, the Court concludes that the factual assertions advanced by Defendants are supported by those records. Plaintiff also does not argue, as a legal matter, that menthol quantities do not meet the criteria to qualifying as FOIA Exemption 4 material. In light of all of these considerations, the Court deems admitted the facts set forth in Defendants' Rule 7.1 Statements. N.D.N.Y. L.R. 7.1(a)(3).

Second, as noted above in Parts I.C.1 and I.C.3 of this Decision and Order, Philip Morris argues, as an independent basis for concluding that FOIA Exemption 4 applies, that its Topic 11 Responses to FDA's Menthol Request Letter are exempt from disclosure because they are

"categorically protected" pursuant to *Critical Mass Energy Project*, 975 F.2d at 878.[16] (Dkt. No. 41, Attach. 1, at 19-23; Dkt. No. 49 at 4 n.4.) The Second Circuit has not adopted this amendment to the test, and this District has never applied it. *Inner City/Cmty. on the Move*, 463 F.3d at 245 n.6. As a result, the Court declines Defendants' invitation to apply it here as an alternative, independent basis for concluding that menthol quantities are not subject to disclosure. Nevertheless, for the reasons stated by Defendants, and based upon the record evidence, the Court finds that the menthol quantity information submitted to FDA (including Topic 11 Responses) satisfies the three-part test employed by the Second Circuit when FOIA Exemption 4 is invoked. *Bloomberg, L.P.*, 601 F.3d at 147; *Inner City Press/Cmty on the Move*, 463 F.3d at 244.

E. Whether the Ingredient Listings Were Properly Withheld Pursuant FOIA Exemption 3

After carefully considering the matter, the Court answers this question in the affirmative, as to 21 U.S.C. § 387f(c), for the reasons stated in the Agency Defendants' memorandum of law. (Dkt. No. 40, Attach. 2, at 19-21 [Agency Defs.' Memo. of Law].)

To those reasons, the Court would add only that Plaintiff does not dispute that the statutes relied upon by Defendants qualify as exemption statutes under FOIA Exemption 3;[17] and, for the

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[16] The Agency Defendants also rely, in part, on the test pronounced in *Critical Mass Energy Project* with regard to information voluntarily submitted to the government. (Dkt. No. 40, Attach. 2, at 15 [Agency Defs.' Memo. of Law].)

[17] Indeed, 21 U.S.C. § 387f(c), by its own terms, unambiguously applies the trade secret exemption codified in FOIA Exemption 4 to the information that TPMs are required to submit pursuant to 21 U.S.C. § 387d. Other courts have concluded that 21 U.S.C. § 331(j) is a FOIA Exemption 3 statute. *See, e.g., Anderson v. Dep't of Health and Human Servs.*, 907 F.2d 936, 950 (10th Cir. 1990). However, as the Agency Defendants note, in this case, FOIA Exemption 3 provides no protection from disclosure beyond that already afforded by FOIA Exemption 4. First, as noted above, 21 U.S.C. § 387f(c) is, by its own terms, dependent upon the applicability of FOIA Exemption 4. Second, 21 U.S.C. § 331(j) prohibits,

same reasons advanced in their arguments that FOIA Exemption 4 applies, the Agency Defendants sufficiently detailed the basis upon which the requested information was withheld pursuant to FOIA Exemption 3. *Carney*, 19 F.3d at 812.

ACCORDINGLY, it is

ORDERED that the Clerk of the Court shall add Santa Fe Natural Tobacco Company, Inc., as an Intervenor-Defendant in this action; and it is further

ORDERED that Defendants' motions for summary judgment (Dkt. Nos. 40, 41, 42) are **GRANTED**; and it is further

ORDERED that Plaintiff's cross-motion for summary judgment (Dkt. No. 45) is **DENIED**; and it is further

ORDERED that Plaintiff's Complaint (Dkt. No. 1) is **DISMISSED**; and it is further

ORDERED that the Clerk of the Court shall enter judgment in favor of Defendants.

Dated: March 2, 2016
Syracuse, New York

Hon. Glenn T. Suddaby
Chief U.S. District Judge

in part, and with limited exceptions, "revealing . . . any method or process which as a trade secret is entitled to protection[.]" "If anything, Section 331(j) is arguably narrower than Exemption 4 in that it is limited to information relating to methods or processes whereas Exemption 4 applies to all trade secret information." *Anderson*, 907 F.2d at 951.