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February 21, 2012

Via Federal Express
Frederick J. Sadler
Director, News Division, Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20814

Re: **Freedom of Information Act Appeal** - Request No. 2011-6586
Jarrow Formulas, Inc.'s Appeal of FDA's January 17, 2012 Decision Not to Provide Information Requested in September 8, 2011 FOIA Request in re: FDA's New Dietary Ingredient (NDI) Draft Guidance

Note: Please forward a written response to Mr. Polisky at the address above left.

Ladies and Gentlemen:

I. Statutory Basis and Timeliness of Appeal

Pursuant to 45 C.F.R. § 5.34 (2011), 21 C.F.R. § 20.62 (2011), other relevant regulations, and applicable case law, Jarrow Formulas, Inc. (JFI) hereby appeals the decision of the U.S. Food and Drug Administration (FDA) to withhold significant information requested in JFI's September 8, 2011 Freedom of Information Act (FOIA) Request (Exhibit 2) in re: FDA's rationales and factual assumptions in connection with the Agency's July 5, 2011 Draft Guidance re: "New Dietary Ingredients" (NDIs). The discoverable information that was denied, but that FDA has a duty to provide, includes FDA's estimates, factual basis, and information as to these requests concerning the Draft Guidance: factual reasons for changes in the law on NDIs, the scientific basis for change in policy on probiotics and synthetic botanicals, costs of various safety tests to be required, and the economic impact of the Guidance as a whole.

As noted in our February 13, 2012 letter to you (attached hereto as Exhibit 6), on January 23, 2012, we received FDA's final response (Exhibit 5, date-stamped January 17, 2012) to JFI's FOIA Request whereby the Agency notified us of its "decision not to provide you with the information you requested." We are now submitting this Freedom of Information Act Appeal within 30 days of our receipt of FDA's letter, as required by law.

II. Background, Importance, and Summary of JFI's FOIA Request

FDA published its New Dietary Ingredient (NDI) Draft Guidance on July 5, 2011, and given its radical departure from the law, immediately faced a firestorm of objections from the dietary supplement industry, respected food and drug counsel, and members of the public.

In sum, JFI, along with many others in the industry, considered FDA's NDI Draft Guidance to be an improper attempt to regulate, indeed to legislate, by Guidance: a Proposed Rule for a new regulation, in the guise of a Guidance. In particular, the Draft Guidance seemed an unlawful endeavor by the Agency to rewrite Sections 4 and 8 of the Dietary Supplement Health and Education Act of 1994 (DSHEA)], for example by shifting the burden of proof with respect to safety and redefining the term "new dietary ingredient." Thus, JFI, as well as other interested parties, saw the Guidance as a clear violation of the Administrative Procedures Act.

In additional, in JFI's view, the Agency further contravened the law in failing at the time of publication to present any facts whatsoever as to the economic impact of its potential policy on the U.S. citizenry and the dietary supplement industry. Furthermore, it was clear that FDA had ignored the potential effect of its policy on the physical health and well being of the American people. The position of JFI, again shared by many, given the extraordinary safety record of supplements vis-à-vis other FDA-regulated products (and no information in the Draft Guidance as to a safety or public health issue to be resolved), was to see this as a shocking example of overreaching regulation, without a compelling purpose.

Thus JFI submitted a Freedom of Information Act (FOIA) Request to FDA on September 8, 2011 (Exhibit 2), asking for detailed, item-by-item answers to 128 questions grouped by topic as follows:

I.A. History of the NDI Draft Guidance and Earlier Versions (Requests 1-14)

I.B. History of the NDI Draft Guidance and FDA Contacts with Other Agencies and Entities (Requests 15-22)

II. Economic, Business and Public Health Impact of the Draft Guidance (Requests 23-38)

III. Testing and Costs of Actual NDI Notifications under the Draft Guidance as it now Stands (Requests 39-47)

IV. Regarding Probiotics and "Live Cultures" (Requests 48-83)

V. Questions on Specific Dietary Ingredients Other than Probiotics (Requests 84-92)

VI. Regarding Safety Issues in the Draft Guidance and in its Background (Requests 93-101)

VII. Regarding the Comment period and FDA's process Toward a Final Guidance (Requests 102-111)

VIII. Regarding Legal Definitions and effects of the Draft Guidance (Requests 112-128)

As JFI stated at the conclusion of the September 8, 2011 FOIA request, time was of the essence, as FDA's answers to these items were crucial for a full and thorough Comment to the NDI Draft Guidance, with a then-deadline less than 2 months away.

But, as outlined below, FDA in its responses to this FOIA ignored the bulk of the requests, providing scant information over the course of an over 4-month period. Of the information provided, some of it was already in the public domain, and other answers were both in the public realm and impossibly general (e.g., referring the requester to a website link). In spite of FDA's failure to provide any answers whatsoever to a majority of the questions and the Agency's insufficient and vague responses to many of the other requests (discussed in detail below), JFI submitted its 45-page Comments to the Draft Guidance on the due date—December 2, 2011.

III. FDA's Delayed and Insufficient Responses Since September 8, 2011

At the time of filing its FOIA request, and indeed before as well (in letters to FDA Dockets Management on August 29 and September 8, 2011, attached as Exhibits 3 and 4), JFI advised the Agency that industry comments to the Guidance could not be complete without meaningful answers to the FOIA. Given the scope and exacting nature of the FOIA request, JFI did not anticipate a full response by FDA within 20 days. However, it soon became clear that FDA did not intend to operate in good faith.

First, much of the information ultimately sent by FDA is already in the public domain and readily obtainable without a FOIA request. Second, with respect to the scant information and volume of documents produced, the agency never directly indicated which information corresponded to which of JFI's 128 specific requests, as required by law. Finally, FDA's final, ultimate response and FOIA denial (stamped January 17, 2012; received January 23, 2012) was delayed until over 6 weeks after the Agency's own December 2, 2011 deadline for Comments to the Guidance.

In its earliest response, FDA sent a 2-disc set with a slew of post-July 5 Comments on the Draft Guidance in letter form from parties concerned with the new policy on NDI's, documents clearly already in the public realm—on FDA's public docket!-- and not truly responsive to any JFI request.

One of the few responsive answers is FDA correspondence between the Agency and Senators Hatch and Harkin. This exchange of letters simply reaffirmed what industry and the FDA all know, i.e., that the Senators strenuously object to any NDI policy that would in essence contravene DSHEA. (Oddly and inconsistently, the Agency offers no specific response or reason for its failure to produce correspondence between FDA and the U.S. House of Representatives or between FDA and other government agencies.)

The bulk of the remaining production consisted of references to publicly available web sites and little in the way of facts that explain the scientific and economic basis on which FDA arrived at its conclusion to radically alter NDI policy. Also, note that a link to a website does not constitute a legally justifiable answer to a FOIA request. Pulling up a particular website does not offer the requester a specific answer, but merely provides general information on a topic. Is the requester then expected to guess or speculate as to which sentence or paragraph in the particular website provides the applicable answer?

In some instances, no material can be found when one views the FDA- referenced web site (e.g., Requests 96-97 regarding Ephedra Alkaloids). In other cases, the web site noted by the Agency citation does not even respond to the specific questions posed (e.g., Requests 50-57 regarding Probiotics).

FDA answered the vast majority of the FOIA requests (90 of 128) with the following statement: "We have searched our files and found no responsive documents." Such an answer is not acceptable, and in some cases not credible. In addition, in comparing responses with the contact person for this FOIA—Sarah Kotler-- on February 3, 2011, Mr. Polisky discovered that there was a letter from FDA (dated November 10, 2011) that we had never received at all. The letter states that FDA is forwarding responses to requests #1, #4 and #14. But again, we never received these responses as to #1 or #4—that is, previous drafts of the Draft Guidance from 2004 to July 2011, and the draft of the NDI Guidance that was current when Dr. J. Sharfstein gave a speech in May 2010 referencing ingredient specific notifications.

As detailed in the attached Catalog (Exhibit 1), with regard to the 128 requested items in JFI's September 8, 2011 FOIA Request, FDA's responses can be divided into three categories:

1. 90 responses: Incredibly, for over two-thirds of documents requested, FDA reported a search, yet failure to find documents. ("We searched our files and found no responsive information.")

2. 26 responses: In most cases, FDA merely referenced already available government web sites (2 of which lead nowhere), with scant production and the bulk of additional information limited to items such as public comment following publication of the Draft Guidance, correspondence between FDA and two U.S. Senators (who, by the way, urged that the Agency not create a policy that veers from the legislative intent of DSHEA;) and exchanges between Dr. Fabricant of FDA and supplement trade associations re: seminars on the Guidance, including slides from one of Dr. Daniel Fabricant's presentations.

3. 12 responses (including responses presumably the subject of the Denial letter): Essentially telling the requester to play a "guessing game," FDA provided nothing and offered no specific reason or rationale for its failure to produce (other than a sweeping checked-box exemption in its January 17 letter, without advising for

which requests it is withholding documents, due to an asserted claim of privilege).

Overall, FDA's responses (or lack thereof) to this FOIA request strain credulity.

First, we find it unbelievable that FDA has no information whatsoever for 90 out of 128 requests—i.e., over two thirds of the requested items. Remarkably, FDA has told us it has no answers, no documents and no facts in connection with many of the key questions posed by JFI:

- Where is the accurate economic impact study of the NDI Draft Guidance, again an omission that alone should render the Guidance null and void?
- Where are the estimates for each safety test recommended by the Draft Guidance?
- Where is the factual or policy justification for attempting to rewrite Section 4 (Safety and the Burden of Proof on FDA) and Section 8 (NDI definition) of DSHEA, establishing a pre-approval mechanism never envisioned or sanctioned by Congress?
- Where is the justification for FDA ignoring the Administrative Procedures Act (specifically the notice and comment rulemaking process) and attempted to create regulation (or indeed, legislation) by "Guidance"?
- Where are the scientific facts supporting new policies as to probiotics, synthetic botanicals, and the statutory meaning of "chemical alteration"?

In sum, in addition to falling far short of its duties and burdens under the FOIA regulations and well-established case law (see Section IV), FDA has forsaken the worthy goal of "transparency in government," publically endorsed and encouraged by the current Commissioner, and across the political spectrum.

IV. Appeal of Incomplete Responses to Specific and Lawful Requests

This Appeal is formally appealing FDA's response to the JFI FOIA on the NDI Draft Guidance, in each of three categories of agency answers.

A. First, it is impossible to fathom that FDA has searched its records and found no documents or factual information whatsoever regarding these JFI requests:

Request 2: All drafts—whether complete or partial—of the current July 5, 2011 Draft Guidance, showing their dates or at least approximate dates and authors thereof, including handwritten notes, annotations and markups, section by section.

Request 5: FDA's decision to regard any new formulation or even a minor change in an existing formulation as an NDI. [How could FDA possibly have no facts to support this radical (and indeed unlawful) departure from existing policy?]

Request 23: Consideration by the Agency of the economic impact of the Draft Guidance. (It is incredulous for FDA to assert it has no facts in this regard.)

Request 25: Projected costs to the consumer of new supplements. (Again, where are FDA's facts in calculating the financial burden the Guidance would impose?)

Request 26: Projected costs to the dietary supplement industry; and Request 38: How the Guidance would affect dietary supplement innovation. (By one industry estimate, each NDIN could cost from $450,000 to $6 million, resulting in a chilling effect on dietary supplement innovation with an attendant effect on the public health. Where is FDA's own factual data on these potential costs and effects? It is impossible to believe that FDA (especially as a self-declared science-based agency) has elected to move blindly forward with no data of its own.)

Requests 30-31 and 34: The likely loss of products from the market place if the Draft Guidance is established policy. (Emory University Law and Economics Professor, Dr. Joanna Sheperd Bailey, estimates a potential 50% decline and some observers predict even greater losses. Where are FDA's own facts in this regard?)

Request 35: How the Guidance would benefit the consumer; Request 36: How the Guidance would negatively impact the health of the American people; and Request 37: How the Guidance would impact health care costs in the U.S. (Again, where are the facts FDA has considered? In enacting DSHEA, Congress in Section 2 strongly endorsed dietary supplements as part of an arsenal to promote better health and reduce staggering health care costs. Supplement research first alerted the nation to how omega-3 fatty acids can prevent heart disease, how selenium can prevent certain cancers, and how folic acid can prevent neural tube birth defects. The Draft Guidance can only be viewed as a frontal assault on public health, including the health of pregnant women and children. Has FDA considered how its Draft Guidance, if enacted, could adversely affect public health and lead to even greater healthcare costs? Again, we have no facts from the Agency.)

B. Second, FDA's scant offerings (for 26 of the 128 requests--with a majority indeed references to publicly obtainable government web sites—all discussed above and in the attached Catalog) can hardly be considered a production in "good faith."

For example, the following request asks for factual information—information that is crucial to understanding the scope and rigor of the Draft Guidance, as well as its expansion of existing regulatory requirements. Unbelievably, with a document that sounds an alarm on supplement "safety," FDA has no facts with respect to this key request:

Request 101: "All FDA documents reflecting communications, discussions, and considerations as to the safety problem(s) of concern with dietary supplements and the precise endpoint(s) —reported deaths, serious adverse events, birth defects, etc.— intended to be remedied or corrected by the Draft Guidance; and all documents

reflecting estimates and mechanisms as to precisely how and to what extent the Draft Guidance would correct those safety problems of concern above."

FDA's answer, shockingly, is: "We searched our files and found no responsive information."

C. Third, FDA asserts a blanket exemption but makes no specific case for how an exemption applies to any of the 128 requested items.

FDA's denial letter received on January 23 concerned the remaining items (12 by our count) to which no answer was sent earlier. These items were not identified by item number. Then the denial letter, which is actually a form letter, has a check next to a box (for "Exemption 5") but fails to specify the exact items for which any privilege is claimed. Further, FDA in no way offers any segregable factual material relating to any items for which a privilege is claimed or reasons why the Agency is unable to separate factual material from what is deems to be "deliberative" processes. Exemption 5 requires a fact-specific inquiry. FDA's responses and the blanket refusal to produce, as stated in its January 17, 2012 letter contain no fact-specific allegations regarding the application of Exemption 5. Further, FDA checks a box for "intra-agency memoranda from which factual information is not reasonably segregable." But again, FDA fails to advise us as to which items fall under this category or why FDA claims it is unable to segregate factual material.

V. FDA's Answers to Probiotics Requests as Prime Example of Insufficiency

The September 8, 2011 FOIA request at issue contains 35 questions on various aspects of Probiotics and "Live Cultures," shown on pages 12 to 18 of the attached Catalog of Responses (Exhibit 1). The reason for this emphasis on probiotic ingredients is that the NDI Draft Guidance introduces a dramatic departure from past FDA policy, including questioning whether probiotics are even valid dietary ingredients. Apparently, the FDA will allow only probiotics that have been consumed as foods to be supplement ingredients; and furthermore, the agency raises safety and toxicity issues, and concerns that certain species might be "pathenogenic." One would have to assume that FDA has considerable science to support such new policies, definitions, and categories, and to justify requiring various rigorous safety and toxicology studies (including for species and strains that have been consumed in foods for decades).

But remarkably, in spite of these assertive new positions and radically new policies, there was a paucity of information sent in response to the 35 questions. For the vast majority of these requests, the FDA response was: "We have searched our files and find **no** responsive information" (emphasis added). For example, that null answer was the response to requests 60 through 68, with the exception of #63 (below).

> 60. All documents indicating and explaining FDA's definition and interpretation of "live cultures" and "live microorganisms."

61. All documents indicating and explaining FDA's definition and interpretation of "viable cultures" and "viable microorganisms."

62. All documents acknowledging that FDA has permitted the manufacturing and sale of probiotic products (dietary supplements and foods) on the U.S. market for over 40 years if FDA had no such category recognizing or approving the sale of such products, and explaining why.

63. All documents covering the last 40 years to the present expressing any sort of level of concern by the FDA that any probiotic products on the U.S. market might be pathogenic, identifying the particular genus, species and strain of each such microorganism of concern, and what said concern of pathogenicity or toxicity might have been or actually was, including the identification of the specific, actual product. (Emphasis added.)

> Response: FDA cites www.regulations.gov/ Keyword/ID: FDA-2000-0126-0006 (The referenced item is a list of 75-Day Premarket Notifications for New Dietary Ingredients.) This answer—a list of NDI Notifications no earlier than 1995-- certainly is not responsive to the request: documentation of concern with pathogenicity in probiotic products in materials from the past 40 years.

64. All documents justifying a requirement that safety studies of post-DSHEA strains of L-acidophilus should be proffered.

65. All documents justifying a requirement that safety studies for other post-DSHEA Bifidobacteria and Lactobacilli probiotic strains be proffered.

66. All documents demonstrating the safety and toxicology difference between a particular probiotic strain consumed from a food source such as cheese, as opposed to consumed in a probiotic supplement.

67. All documents reflecting the details of the safety studies that should have been conducted for a "new" strain of acidophilus.

68. All documents reflecting the anticipated cost of such studies for the Request above. (Emphasis added.)

For all of the questions above, the FDA did not assert any privilege or exemption: clearly the responses called for are in the realm of facts (biochemical, epidemiological, etc), not of agency deliberations. The questions ask for definitions (legal and scientific), risk factors, safety studies, and estimated costs. Yet no such responsive facts were provided. (FDA does provide a web site that leads to a transcript of a more than 11-year old "Food Advisory Committee Meeting on Probiotics," but this document in no way answers JFI's specific factual questions.)

The above examples from the probiotic section of the FOIA at issue are representative of the entire body of FDA responses. At the most basic level: If FDA can give no definition for "live cultures" and "live microorganisms," then how can these terms be linked to probiotics, and then summarily reclassified as drugs or biologics? The unmistakable conclusion is that either: A. There is no factual, scientific support for the agency's handling of probiotics in the NDI Draft Guidance; or B. The FDA has not made a good faith effort in responding to this FOIA Request of September 8, 2011.

As part of this Appeal, our client hereby repeats these Requests 48 through 83, and in particular, asks FDA to provide any and all information supporting a scientific, legal, and cultural basis for stating and implying that probiotics are not or may not be a dietary ingredient permissible for supplements.

VI. Outright Denial of Several Items with a Blanket Assertion Of Exemption 5 is Not Legally Sufficient.

First, inter-agency or intra-agency communications are not per se non-disclosable. We note that FDA, in response to a 2009 FOIA by JFI regarding the GAO's recommendations on "improved oversight" of supplements, produced both inter-agency documents and intra-agency documents between FDA and the GAO. Both FDA's internal documents and its reply to GAO show that FDA strongly disagreed with many of the GAO's suppositions. FDA saw no "safety" issues with supplements that would warrant overturning DSHEA or instituting a system of "preventive controls" that in essence would amount to an unlawful pre-approval requirement. In sum, FDA's memorandum to GAO, produced in response to JFI's FOIA, revealed that the Agency:

1. Dismissed GAO's notion that registration of all supplement firms as well as information on the identity and composition of the products they market would enhance supplement safety.
2. Rejected GAO's recommendations that supplement manufacturers report all adverse events as such a policy would clog the system and prevent FDA from proper focus on serious adverse events.
3. Failed to in any way endorse revision of the Food, Drug & Cosmetic Act with respect to the legal definition of a new dietary ingredient (NDI) as set forth in Section 8 of DSHEA

For the record, GAO forged ahead with its report one week later, ignoring the FDA input the GAO had requested.

The above production is an example of what the public can and must learn.

The Denial letter maintains that certain requested materials are exempt from FOIA under 5 U.S.C. Section 552(b)(5). This exemption is commonly referred to as Exemption Five. However, case law requires that for Exemption 5 to apply, the deliberations must be "direct", not merely indirect, or implied, or merely reflected in

certain documents. Historically, the courts have established two fundamental requirements, both of which must be met, for the deliberative process privilege to be invoked. First, the communication must be predecisional, i.e., "antecedent to the adoption of an agency policy." Citizens For Responsibility and Ethics in Washington v. National Archives and Records Admin., 583 F.Supp.2d 146, 157 (Dist. D.C. 2008) (internal citations and quotations omitted) (quoting Jordan v. United States Dep't of Justice, 591 F.2d 753, 774 (D.C. Cir. 1978) (en banc)). Second, the communication must be deliberative, i.e., "a direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters." Vaughn v. Rosen, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975). The burden is upon the agency to show that the information in question satisfies both requirements. Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980).

5 U.S.C. Sec. 522(b) requires that any reasonably segregable portion of a record be provided to a requester after deletion of any exempt portions. As stated in Krikorian v. Department of State, 984 F.2d 461, 467 (D.C. Cir. 1993), *quoting* Mead Data Cent., Inc. v. U.S. Dep't of Air Force, 566 F.2d 242, 260 (D.C. Cir. 1977), "the focus in the FOIA is information, not documents, and an agency cannot justify withholding an entire document simply by showing that it contains some exempt material." (emphasis added). Thus, assuming *arguendo* that Exemption 5 applies in connection with any of the JFI requests, the exemption does not protect factual data or matters that may be reasonably segregated from material that is confidential.

Thus, for those requests for which FDA does claim a "privilege" (again, not discernable here because FDA asserts a general "checked box" exemption without a clearly delineated item-by-item response), FDA must, of course, produce a "Vaughn index." A Vaughn index, first sanctioned in Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974), must: (1) identify each document withheld; (2) state the statutory exemption claimed; and (3) explain how the disclosure would damage the interests protected by the claimed exemption. Citizens Commission on Human Rights v. FDA, 45 F.3d 1325, 1326 n.1 (9th Cir. 1995). The detailed affidavit "permit(s) the court system effectively and efficiently to evaluate the factual nature of the disputed information. John Doe Agency v. John Doe Corp., 493 U.S. 146, n.2 (1989), *quoting* Vaughn, 484 F.2d at 826.

Again, the index must describe with specificity the material withheld and justify why each responsive document is exempt. King v. Dept. of Justice, 830 F.2d 210, 221 (D.C. Cir. 1987). Clearly, with its blanket "checked-box" letter of January 17, 2012, FDA has neither identified each specific document for which it claims a privilege, nor stated the statutory exemption that applies to each specific document. Next, when creating a Vaughn index, "[a] withholding agency must describe each document or portion thereof withheld, and for each withholding, it *must* discuss the consequences of disclosing the sought-after information. Id. at 223-224. Furthermore, FOIA exemptions are to be narrowly construed. Wolf v. CIA, 473 F.3d 370, 374 (D.C. Cir. 2000).

As to any items for which FDA might assert a privilege, the Agency, of course, still has a duty to segregate factual material from any claimed deliberations. FDA prides itself on being a "science-based" entity. Yet FDA has ignored many of our questions asking for facts as to the scientific basis for a plethora of FDA's assumptions and conclusions. Here, JFI is not asking about the deliberative process, but rather, simply seeking facts. FDA has a duty, in a FOIA response, to separate fact from what it deems to be privileged deliberation. Again, FDA has failed in this regard.

We thus hereby request a description of each document withheld, its relation to Exemption 5 and the consequences to FDA as well as to the supplement industry and the American public in the Agency's refusal to release any requested information.

At a more basic level, to show that its FOIA search was reasonable, FDA must demonstrate that when viewing the facts in the light most favorable to the requestor, it has conducted a search reasonably calculated to uncover all relevant documents. Once again, FDA has failed in this regard.

As stated above, in many instances, we are asking for the facts underlying a decision, and not the deliberative process. Given the scope and complexity of the Guidance, its potentially transformative effect on a multi-billion dollar industry, and capacity for negatively impacting both the physical and economic health of the American people, there is added imperative for demanding production in this case.

VII. Specific Requests of this Appeal

FDA must be compelled to respond to JFI's September 8, 2011 FOIA and at the very least, be required to release all factual information relating to the 128 requests therein. This is the agency's duty and burden under the clear case law on Exemption 5. Specifically, for all the legal and policy reasons above, this Appeal makes the following Requests as to JFI's September 8, 2011 FOIA letter:

1. All factual documents and factual sections in claimed deliberative documents that respond to the items answered before the January 17 denial letter.
2. A list of the specific items referred to in the January 17 denial letter.
3. For these items in 2., above, FDA's statement of which privilege or exemption applies, and its argument or citation for why such documents or information are non-disclosable.
4. A Vaughn index for all the items and documents referred to in the January 17 denial letter as withheld.
5. All factual materials and information in the "remaining items" referenced in the January 17 denial letter.

6. In any documents in which FDA is claiming that deliberative process information is present with factual information, a disclosure and production of those documents, with the deliberative material redacted.

If this Appeal is granted, please reply in writing concerning which items will be answered or further answered, which documents will be forthcoming, and when we can expect those documents or information to be released and produced.

A denial of this Appeal by silence is not acceptable (that is, via no reply for 30 days—the regulatory 20 days plus a 10-day extension). If this Appeal is denied, we request in writing the specific legal reasons for denial—item by item, especially for the "remaining items" referenced in the denial letter received on January 23, 2012. In addition, we hereby request a detailed Vaughn index, as described above.

Any questions may be addressed to Mr. Polisky at 917-837-9600.

Sincerely,

P. Scott Polisky

(Letter signed in blue ink and
sent to HHS by Scott Polisky)

P. Scott Polisky

Susan D. Brienza

Attachments

cc: Jarrow L. Rogovin
Dietary Supplement Manufacturers and Marketers Association (DSMMA)
Todd Harrison, Venable LLP, General Counsel for DSMMA
Ioannis Misopoulos, Executive Director, International Probiotic Association
George Paraskevakos, President, International Probiotic Association