

December 12, 2016

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1030  
Rockville, MD 20852

Re: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry, 81 Fed. Reg. 53486 (Aug. 12, 2016), Docket No. FDA-2011-D-0376 (“2016 Draft Guidance”)

The Consumer Healthcare Products Association (“CHPA”) is the leading national trade association representing manufacturers and distributors of over-the-counter drugs and dietary supplements. Our association is committed to maintaining the highest levels of safety in the manufacture and regulation of dietary supplements and therefore appreciates this opportunity to provide comments on this 2016 Draft Guidance.

CHPA believes that FDA’s revised 2016 Draft Guidance is an important step in helping to improve manufacturer understanding of, and compliance with, the new dietary ingredient (“NDI”) notification requirement in Section 413 of the Federal Food, Drug, and Cosmetic Act (“FFDCA”).

But there are also proposals in this document that may impede product/ingredient innovation by responsible companies and make it difficult to introduce new products. Some of the 2016 Draft Guidance content thus runs counter to the essence and intent of the Dietary Supplement Health and Education Act (“DSHEA”).

CHPA looks forward to engaging with FDA in a cooperative, collaborative effort to clarify and improve the regulation of dietary supplements.

We offer the following principal comments:

1. A rational path is needed for the identification and acceptance of pre-DSHEA (“grandfathered”) dietary ingredients. The 2016 Draft Guidance essentially imposes DSHEA’s post-1994 “dietary supplement” definition on pre-1994 ingredients, and includes manufacturing and chemical identity requirements which are not consistent with DSHEA.

- a. We applaud FDA for offering to establish an authoritative list of such ingredients but urge the Agency to establish a joint industry/government process to accomplish this work. We look forward to participating in that effort.
  - b. In the meantime, FDA should announce a policy of enforcement discretion for long-available ingredients. This would allow a company the opportunity to provide information to support the grandfathered or alternate (*e.g.*, GRAS or self-GRAS) status of a questioned ingredient.
  - c. Instead of requiring the industry to provide manufacturing information that may not be available or realistic to obtain, FDA should rely on the DSHEA safety provisions in Section 402(f) of the FFDCFA to ensure product safety. Manufacturing information is not currently a requirement to demonstrate grandfathered status for an ingredient. Rather, such status is determined solely on the basis of evidence that the ingredient was marketed (*e.g.*, a dated pre-October 15, 1994 invoice or advertisement).
2. FDA should withdraw its effort to eliminate all innovative products, including synthetics and probiotics, that are not traditional vitamins, minerals or herbs under section 201(ff)(1)(E) of the FFDCFA. Other “dietary substance[s]” does not mean other “nutritional substances.” Congress made that clear.<sup>1</sup> This provision in FDA’s 2016 Draft Guidance will all but eliminate innovation.
  3. FDA should make the NDI notification process a manageable one. FDA’s approach to “chemical alteration” and the consultation that FDA proposes to seek represents an impossible hurdle for most responsible companies. Instead of introducing unclear and overly burdensome information requirements, FDA should rely on the DSHEA safety provisions, which were explicitly drafted to provide a multi-layered safety net.
  4. Self-affirmed GRAS determinations are valid for dietary supplements, just as they are for foods. FDA should acknowledge safety determinations meeting well-articulated criteria as an alternative to the NDI notification instead of rejecting the self-affirmation process completely. We ask that FDA confirm its recognition of GRAS self-affirmations in the NDI notification context.
  5. While we applaud the innovative addition of the NDI Master File, the system will not work unless FDA also recognizes trade secret protection for applicable safety data.

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<sup>1</sup> Senate Report No. 103-210 at 13 (1994).

6. The NDI provision, Section 413, addresses *dietary ingredients*. FDA should consistently use an ingredient-focused approach to require NDI filings for all companies offering for sale any given dietary *ingredient*, relying on previous safety submissions only where there is a Dietary Supplement Master File.
7. It is not feasible or appropriate for FDA to simultaneously adopt a supplement-focused approach in which companies must file NDI notifications for every new dietary supplement *product* that contains a previously notified NDI. FDA's extensive safety provisions under Section 402(f) are available where FDA has safety concerns about the impact of combining ingredients.
8. FDA should consider CODEX safety standards in determining appropriate safety substantiation pathways to ensure that global companies are not subject to significantly varying requirements.

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**I. FDA Must Develop a Rational Path to Identify and Accept Grandfathered Dietary Ingredients**

**A. Grandfathered Ingredients Are Not Subject to the Post-1994 Definition of Dietary Ingredient**

Establishing the scope of grandfathered ingredients has long been the subject of disagreement between FDA and stakeholders. FDA's 2016 Draft Guidance inappropriately attempts to narrow this category through the retroactive application of DSHEA's "dietary ingredient" definition. Thus, FDA states that a pre-1994 substance must have been used as a "dietary ingredient" *according to the DSHEA definition that was introduced in 1994*. FDA adds further that ingredients that do not fall within this retroactively-applied definition will be considered NDIs subject to the notification requirement.<sup>2</sup>

CHPA asks FDA to withdraw this approach. The retroactive application of the statute has no basis in law and contravenes the norms of statutory interpretation. FDA offers little justification for its approach.

**B. FDA Should Establish a Joint Panel to Generate an Authoritative List of Grandfathered Ingredients**

CHPA applauds FDA's proactive offer to establish an authoritative list of grandfathered ingredients and would like to work *with* FDA to establish such a list.

This offer comes after many years of deliberation on the scope of grandfathered ingredients. After the passage of DSHEA in 1994, several industry groups – including the Council for Responsible Nutrition ("CRN"), the National Nutritional Foods Association (now the Natural Products Association ("NPA")) and the American Herbal Products Association ("AHPA"), among others – worked with their members to compile lists of dietary ingredients that they knew to be present on the market as of October 15, 1994.

FDA has consistently taken the position that such lists are not *per se* indicative of grandfathered status and has instead placed the burden on industry to substantiate claims of grandfathered status with evidence in each individual case. Industry has long disputed this position based on clear statutory language that FDA – not industry – bears the burden of proof to demonstrate the NDI status of an ingredient.<sup>3</sup>

In the 2016 Draft Guidance, FDA takes a positive step by offering to establish an "authoritative list of pre-DSHEA ingredients, based on independent and verifiable data" submitted by industry.<sup>4</sup> However, FDA included no means to make this authoritative list a reality. We therefore suggest that FDA:

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<sup>2</sup> 2016 Draft Guidance at 14

<sup>3</sup> Federal Food, Drug & Cosmetic Act, Sections 413 and 402(f)

<sup>4</sup> 2016 Draft Guidance at 19

- (1) establish a Joint Panel, consisting of representatives from FDA and industry; and
- (2) task that Joint Panel with evaluating evidence of grandfathered status submitted by stakeholders, with regular meetings to review evidence submitted.

Use of a Joint Panel to establish grandfathered status was favorably discussed in a series of FDA-stakeholder meetings held in 2012 and 2013.<sup>5</sup> As agreed by most stakeholders present at those meetings, a Joint Panel approach would leverage available evidence of marketing of dietary ingredients, ensure all stakeholders have a voice in weighing the evidence, and provide transparency about the process.

### **C. FDA Should Clarify the Scope of Material Needed to Establish Grandfathered Status**

In this context, CHPA requests that FDA clarify that the Joint Panel needs only one document to establish evidence of *marketing* of a dietary ingredient for that ingredient to have grandfathered status.

Thus, a single sales brochure or advertisement may definitively demonstrate the “marketing of the ingredient” in the U.S.

CHPA urges FDA to expand its list of the individual pieces of evidence that can be relied upon to confirm pre-DSHEA marketing status. In the 2016 Draft Guidance, FDA states that such evidence could include, “sales records, bills of lading, sales contracts, manufacturing records, commercial invoices, magazine advertisements, mail order catalogs, or sales brochures.”<sup>6</sup> CHPA suggests that FDA acknowledge that each piece of evidence, by itself, definitively establishes grandfathered status. FDA should also add Certificates of Analysis to this list, because such documents confirm that a product has been manufactured for marketing.

Further, FDA should make clear that affidavits attesting to the existence of Certificates of Analysis will be acceptable, in recognition of the fact that such documents may contain trade secret information. In addition, when a marketed product is discussed in a pre-DSHEA journal, magazine or newspaper article, book, or patent, such references should be permitted as definitive evidence of pre-DSHEA marketing status. In addition, we would also propose that FDA include the *Herbs of Commerce*<sup>7</sup> as sufficient documentation of pre-1994 marketing, provided that the plant part is specified in the listing.

Clarity around the scope of evidence required will allow the Joint Panel and industry to move efficiently toward establishing an authoritative list.

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<sup>5</sup> FDA meetings with the dietary supplement trade associations (American Herbal Products Association; Consumer Healthcare Products Association; Council for Responsible Nutrition; Natural Products Association; United Natural Products Alliance) occurred on July 31, 2012; October 16, 2012; April 2, 2013; and July 16, 2013

<sup>6</sup> 2016 Draft Guidance at 18

<sup>7</sup> American Herbal Products Association, *Herbs of Commerce*; 1<sup>st</sup> Edition, published 1992

**D. FDA Should Announce a Policy of Enforcement Discretion for Long-Available Dietary Ingredients**

As it works toward an authoritative list of grandfathered ingredients, FDA should announce a policy of enforcement discretion while that process is proceeding for those dietary ingredients that have long been available on the U.S. market, and have been widely used with no known serious safety risks. Doing so would allow a company the opportunity to provide information to support the grandfathered or alternate (*e.g.*: GRAS or self-GRAS) status of a questioned ingredient. A policy of enforcement discretion toward such ingredients would focus the efforts of the Joint Panel on ingredients with a less well-established safety profile and would serve FDA's stated aim of helping the "dietary supplement industry understand and comply with section 413 of the FD&C Act and the NDI regulation."<sup>8</sup>

Congress "grandfathered" pre-DSHEA dietary ingredients because their safety was presumed based on a long history of safe use. There is no safety benefit to consumers in requiring that FDA, the Joint Panel, or industry expend valuable resources demonstrating anew that ingredients such as these were available prior to October 15, 1994. A policy of enforcement discretion will advance FDA's goal of helping "the dietary supplement industry understand and comply with section 413...".

**E. FDA Must Not Impose an Impossible Burden on Industry of Demonstrating the Manufacturing Process for Grandfathered Ingredients**

FDA should revise the response to its newly added Question IV.A.12 of the 2016 Draft Guidance ("If I change the manufacturing process for a dietary ingredient that was marketed in the U.S. prior to October 15, 1994, does that make the ingredient an NDI?") to make clear that the manufacturing process used to produce a grandfathered ingredient is not relevant to its grandfathered status, nor can changes to the manufacturing process alter this status. FDA should clarify that a manufacturing process, and changes to any such process, are relevant only to the extent they bear on the safety of the grandfathered ingredient. Thus, for example, a water or ethanol extract of a grandfathered botanical ingredient should not be considered a NDI.

FDA's response to Question IV.A.12 raises questions about the Agency's approach. Therein, FDA states that "[m]anufacturing changes that alter the physicochemical structure or properties, purity and impurities, or biological properties" of a grandfathered ingredient can cause it to be a NDI – rather than a grandfathered ingredient.<sup>9</sup>

This statement has no basis in the statute. Section 413(d) defines dietary ingredient solely on the grounds of whether it was marketed or not; there is no mention of the ingredient's physicochemical structure, purity, biological properties, serving level, and/or source. Moreover, requiring industry to identify specifications for ingredients first marketed prior to October 1994, a period that pre-dates electronic record-keeping, often by parties that no longer exist, is unlikely to produce a meaningful list of ingredients.

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<sup>8</sup> 2016 Draft Guidance at 12

<sup>9</sup> 2016 Draft Guidance at 21

Even more, there is no indication in the legislative history that Congress deemed any of these characteristics relevant to the identification of a grandfathered dietary ingredient. In fact, and contrary to its response to Question IV.A.12, FDA acknowledged that such factors are not pertinent to grandfathered ingredients in hearings before Congress:

When Congress passed DSHEA, it created a unique regulatory framework for dietary supplements. Its purpose was to strike the right balance between providing consumers access to dietary supplements and truthful information about them, while preserving regulatory authority for FDA to take action against supplements that present safety problems or false or misleading labeling.

As you know, the regulation of dietary supplements is, for the most part, a post-marketing program. Since Congress considered dietary ingredients marketed prior to the passage of DSHEA to be safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like regular foods (e.g., fresh fruits and vegetables, processed foods and beverages, and seafood). Should safety problems arise after marketing, the adulteration provisions of the statute come into play.<sup>10</sup>

Thus, as with foods, the manufacturing process – and with that, the physicochemical structure or properties, purity and impurities, biological properties, serving level, and/or source – of a grandfathered ingredient need not be established by industry to defend grandfather status.

At the same time, CHPA agrees with FDA that the safety of grandfathered ingredients, and the dietary supplements containing them, is critically important. However, FDA has already articulated a policy for addressing post-marketing safety issues arising from manufacturing processes in its Guidance, “Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives” (June 2014) (“Manufacturing Guidance”). Therein, FDA directs industry to undertake a detailed analysis to evaluate whether changes in manufacturing methods alter the safety profile of an ingredient. FDA should clarify that this approach is equally applicable to assessing the safety of grandfathered dietary ingredients.

Use of *nanotechnology* should be subject to the same analysis. CHPA objects to FDA’s assertion in the 2016 Draft Guidance that “a manufacturing process change intended to produce an ingredient with particles in the 1 nm [nanometer] to 100 nm (approximate) nanoscale range may alter the chemical or molecular composition or structure of the NDI,” requiring a new NDI notification to be filed.<sup>11</sup>

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<sup>10</sup> Statement of Joseph A. Levitt, Esq. Director, Center for Food Safety and Applied Nutrition, FDA, “Six Years After the Establishment of DSHEA: The Status of National and International Dietary Supplement Research and Regulation”: Hearing Before the House Committee on Government Reform, 107<sup>th</sup> Cong. 136-37 (2001).

<sup>11</sup> 2016 Draft Guidance at 22

FDA has taken the position elsewhere that the use of nanotechnology is only a concern if it results “in product attributes that differ from those of conventionally manufactured products,” raising safety issues.<sup>12</sup> FDA should apply this same approach in the grandfathered ingredient context. Thus, use of nanotechnology in processing a grandfathered ingredient would only result in an NDI if the product attributes of the resulting substance differ from the grandfathered ingredient in a manner that affects safety.

Thus, our position is that a manufacturing process change for a grandfathered dietary ingredient should only be considered to create an NDI if that process affects the safety of the ingredient. The June 2014 FDA Manufacturing Guidance, wherein FDA provides details on undertaking an analysis of changes in manufacturing methods and their effect on an ingredients safety profile, could be used to assess the safety of grandfathered dietary ingredients.<sup>13</sup>

#### **F. Safety Concerns Are Better Addressed by DSHEA’s Multiple Safety Provisions**

Where FDA suspects there are safety issues, it should rely on the multiple, layered safety provisions introduced by DSHEA rather than seek to impose overly burdensome specification requirements on grandfathered dietary ingredients.

In the first instance, Section 402(f)(1)(A) provides that a dietary supplement is adulterated if it “presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or . . . under ordinary conditions of use.” Moreover, FDA can take action under Sections 402(f)(1)(C) or (D) if a grandfathered ingredient or changes to the grandfathered ingredient result in a dietary supplement that poses “an imminent hazard to public health or safety” or if it contains any “poisonous or deleterious substance which may render it injurious to health” “under the conditions of use recommended or suggested in the labeling.” Taken together with FDA’s enforcement authority under Section 301 of the FFDC, these statutory sections provide the Agency with broad powers to address any safety issue that arises.

In this context, CHPA wishes to re-emphasize a significant point made at the four meetings with FDA to discuss the original 2011 Draft Guidance: FDA bears the burden of proof under Section 402(f) on any safety issue with respect to dietary supplements. That means that FDA must first assert that a dietary ingredient lacks adequate safety data, after which the burden of going forward is placed upon the company to produce whatever information it has about grandfathered status. But at the end of the day, it is still FDA’s burden to prove by a preponderance of evidence that there is inadequate safety data. Accordingly, FDA should rely upon its own safety databases (*e.g.*, post-marketing adverse event database) and scientific information to raise specific questions with respect to specific ingredients rather than placing on industry in the first instance the burden of producing detailed information that may simply not be available.

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<sup>12</sup> 2014 Manufacturing Guidance at 14

<sup>13</sup> *Id.*

## II. FDA Must Correct its Continued Misreading of Section 201(ff)(1)(E): Other “Dietary Substance[s]”

As part of its discussion of synthetic herbs, FDA reiterates a position that it had internally rejected<sup>14</sup> in 2003: that the DSHEA definition of dietary ingredient in Section 201(ff)(1)(E) – “dietary substance” – only means substances that are already present in “food or food components that humans eat as part of their usual diet” and that have been “used as a lawfully marketed ingredient in the conventional food supply.”<sup>15</sup> For FDA, this section acts a *de facto* exclusion of new synthetic versions of botanical ingredients and other new synthetic ingredients intended to supplement the diet.

CHPA sincerely believes that this is the greatest hurdle with respect to product innovation in FDA’s 2016 Draft Guidance and is, in fact, one of the most inconsistent positions that FDA has taken against the intent of DSHEA.

The point of Congress’ insertion of a separate definition for non-food ingredients was to anticipate expansion and innovation in dietary supplement development. Section 201(ff)(1)(E) should instead open the door to innovative dietary supplements, including synthetic ingredients and probiotics.

In this regard, the Senate Report was explicit: It identified Coenzyme Q10, which was commonly synthesized, glucosamine, and primrose oil as examples of substances that should fall under Section 201(ff)(1)(E).<sup>16</sup> None of these products are generally consumed as food.

Equally important, Congress replaced the term “nutritional substance” used in earlier versions of Section 201(ff)(1)(E) with the term “dietary substance,” *specifically* to emphasize the point that Section 201(ff)(1)(E)’s scope was **not** limited to ingredients considered to have nutritional value.<sup>17</sup>

The only limit placed by Congress on Section 201(ff)(1)(E) is the *intended use* of the dietary ingredient. This point is made explicit in the Senate Report accompanying DSHEA:<sup>18</sup>

a product intended for use to supplement the diet with any vitamin, mineral, herb, other botanical, amino acid, or other substance, including a concentrate, metabolite, constituent, extract, or combination of two or more of such ingredients, in order to increase the total dietary intake is subject to regulation as a food and not a drug.

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<sup>14</sup> Letter from Susan J. Walker, M.D., Acting Dir., Div. of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, Ctr. For Food Safety and Applied Nutrition, FDA, to Mr. I. Scott Bass, Esq. and Ms. Diane C. McEnroe, Esq. Sidley Austin Brown & Wood (Mar. 12, 2003).

<sup>15</sup> 2016 Draft Guidance at 38-39

<sup>16</sup> Senate Report No. 103-410 at 13 (1994)

<sup>17</sup> *Id.*

<sup>18</sup> Senate Report No. 103-410 at 13 (1994); emphasis added

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In general, it is the intended use of a particular finished product (as shown by representations made for it in promotional materials) that determines whether than [sic] product and its ingredients are subject to regulation as a food or as a drug. If a vitamin product or an herbal product, for example, is represented for use as a ‘dietary supplement,’ it is a food; if it represented to cure, mitigate, treat, or prevent a disease, it is a drug.

The Congressional intent is clear: there is no rationale for FDA to take the position that Section 201(ff)(1)(E) of the FFDCA precludes synthetics or probiotics as dietary ingredients. The appropriate reading of the statute is that a substance, including a probiotic or synthetic ingredient, “for use by man to supplement the diet” is appropriately a “dietary ingredient.” Accordingly, if that probiotic or synthetic ingredient is appropriately determined to be an NDI under Section 413, an NDI notification would be required.

### **III. Synthetic Herbs: FDA Should Correct Its Limited and Inappropriate Application of 201(ff)(1)(F)**

In the 2016 Draft Guidance, FDA further claims that Section 201(ff)(1)(F) includes only those concentrates, metabolites, constituents, extracts or combinations of ingredients that fall under its interpretation of Sections 201(ff)(1)(A)-(E), and are naturally occurring rather than synthetic.<sup>19</sup>

This is also contrary to clear legislative intent. Section 201(ff)(1)(F) was intended to be interpreted broadly. Thus, Congress continued to add categories of potential ingredients during the legislative drafting process in an attempt to bar FDA from continuing its anti-botanical approach. The initial S. 784 Hatch bill included only a “concentrate or extract” in the Section 201(ff)(1) categories; “constituent” and “combination” were subsequently added to the legislation as further protection against FDA seeking to bar botanical-derived dietary ingredients. Congress finally added “metabolite” with no further legislative discussion.

#### **A. FDA Has Previously Recognized the Breadth of the Dietary Ingredient Definition and Accepted Synthetic Dietary Ingredients**

FDA *itself* has previously affirmed that it recognizes substances as dietary ingredients, regardless of the fact that they are commonly synthesized in dietary supplements.<sup>20</sup>

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<sup>19</sup> 2016 Draft Guidance at 39

<sup>20</sup> 21 CFR §101.9(k)(4); 38 *Fed. Reg.* 6951, 6958 (Mar. 14, 1973) (a food may not suggest “that a natural vitamin in a food is superior to an added or synthetic vitamin”). See also 62 *Fed. Reg.* 49826, 49841 (Sept. 23, 1997) (FDA is “aware of nothing that establishes that a claim of difference between the natural and synthetic version of the same form of a nutrient is not misleading”). Section 411 of the FFDCA explicitly recognizes that both vitamins and minerals may include synthetic or natural ingredients and has specifically prohibited FDA from limiting the combination or number of any synthetic or natural vitamin, mineral, or “other ingredient of food” in a food for special dietary use. See FFDCA 411(a)(1).

Further, in rulemaking under the Nutrition Labeling and Education Act of 1990, FDA took the position that a broad range of dietary ingredients is contemplated in dietary supplements:

. . . the legislative history of “other nutritional substances” reveals that its coverage is broad and could, in appropriate circumstances, include dietary ingredients without RDI’s or DRV’s (136 Congressional Record S16609 (October 24, 1990)). In a discussion between Senators Metzenbaum and Symms before the passage of the 1990 amendments, Senator Symms stated: \* \* \* ‘What follows is a list of a few of the items and foods that I believe would fall under the “other similar nutritional substances” category established by this bill: Primrose oil, black currant seed oil, coldpressed flax seed oil, “Barleygreen” and similar nutritional powdered drink mixes, Coenzyme Q 10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium-EAP (colamine phosphate), glandulars, hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), nutritional antioxidants such as superoxide dismutase (SOD), and herbal tinctures.’ Based on this colloquy, the agency interprets the list of dietary ingredients that fall under the definition of “dietary supplement” in section 201 (ff) of the act as an explication of “other similar nutritional substances.”

62 Fed. Reg. 49859, 49859-60 (Sept. 23, 1997) (emphasis added).

To this end, FDA has previously accepted NDI notifications for synthetic botanical ingredients without objection, among them an NDI notification from Roche Vitamins, Inc. in March 2001 for synthetic zeaxanthin (NDI Report No. 96) and from HOB Ireland, Lt. in January 1999 for synthetic (-)-hydroxycitric acid (NDI Report No 35).

There is no reason for FDA now to change this position. A synthetic version of a botanical concentrate, constituent or extract should be considered a dietary ingredient subject to the same statutory NDI analysis and safety standards as any other dietary ingredient, as long as it is chemically identical to the natural version of the botanical concentrate.

## **B. CHPA Objects to FDA’s Approach on Vinpocetine**

CHPA also objects to FDA’s reliance on a limited interpretation of FFDC A Section 201(ff)(1) with regard to vinpocetine.<sup>21</sup> Despite the lack of any new information impacting the safety of vinpocetine which was not available when the first NDI notification for vinpocetine was submitted nearly 20 years ago, FDA has tentatively concluded that, despite having accepted five NDI notifications for synthetic vinpocetine, this dietary ingredient is barred: (1) because it is a synthetic version of a botanical ingredient; and (2) by the “race-to-market” provisions in Section 201(ff)(3) because there was an IND filed and substantial clinical investigations undertaken and made public prior to receipt of the NDIs.

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<sup>21</sup> Request for Comment on the Status of Vinpocetine, 81 *Fed. Reg.* 61700, September 7, 2016

CHPA believes that a valid demonstration that there was a public disclosure of an IND having been filed and clinical studies conducted prior to the NDIs would provide a sufficient basis under Section 201(ff)(3) for removing vinpocetine from the market. CHPA objects to FDA's interpretation of FDCA Section 201(ff)(1) in its Federal Register notice regarding vinpocetine. In CHPA's view, FDA's interpretation of Section 201(ff)(1)(E) is contrary to Congressional intent and there is no justification for FDA to invoke this misinterpretation in its rationale regarding vinpocetine.<sup>22</sup>

#### **IV. FDA Should Establish Clear Criteria for Manufacturing Processes That Do Not “Chemically Alter” An Ingredient**

The 2011 Draft Guidance was widely criticized for taking the view that the Congressional Statement of Agreement, 140 Cong. Rec. S14801 (daily ed. Oct. 7, 1994), represented a complete list of manufacturing processes that do not chemically alter a food for purposes of Section 413(a)(1). In a positive change, FDA acknowledges that the list in the Congressional Statement of Agreement represents “examples of manufacturing processes that do not involve chemical alteration, but not necessarily a complete list of such processes.”<sup>23</sup> FDA states that it is “willing to consider arguments supported by science demonstrating that particular manufacturing processes do not actually result in a chemical alteration or have any effect on the safety profile of the ingredient.”<sup>24</sup>

CHPA appreciates FDA's flexibility. At the same time, FDA's position in the 2016 Draft Guidance could be improved to enhance its usefulness in the determination of when an ingredient would be considered chemically altered.

FDA should improve its guidance to make the NDI notification process a more manageable one. FDA fails to provide actual criteria for assessing when processing steps do not result in chemical alteration. Instead, the Agency appears to require consultation each time a processing technology is considered, and places the burden on industry to come to FDA before adopting any such technology to present “arguments supported by science demonstrating that particular manufacturing processes do not actually result in a chemical alteration or have any effect on the safety profile of the ingredient.”<sup>25</sup> This process presents an unreasonable burden on companies and leaves considerable uncertainty about supporting data FDA would require to allow acceptable processing methodologies.

The standard set for evaluation of chemical alteration in Section IV.B.5 of the 2016 Draft Guidance is vague:

We intend to evaluate applicable new technologies or processes based on our guidance on chemical alteration as set forth in this document. We also intend to consider whether or not the technology

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<sup>22</sup> CHPA Comments to FDA on the status of vinpocetine, November 7, 2016

<sup>23</sup> 2016 Draft Guidance at 26 (emphasis added)

<sup>24</sup> *Id.* at 28

<sup>25</sup> *Id.* at 28

or process would affect the safety profile of the dietary ingredient and the dietary supplement in which it is used.

A better approach would be for FDA to articulate a list of criteria for evaluating whether a manufacturing process results in chemical alteration. To its credit, FDA begins such a list in the 2016 Draft Guidance with the following:<sup>26</sup>

FDA considers a process that does not result in chemical alteration to mean a process that: (1) involves an ingredient composed of one single raw material, or derived from a single raw material using a manufacturing process that involves only physical steps (e.g., water extraction and condensation); and (2) does not involve attempts to selectively increase the concentration of particular active ingredients or cause a chemical reaction (other than esterification) that would modify the covalent bonds of any substance in the original material.

FDA goes on to state that it accepts that these processing steps are “unlikely to affect the safety profile of the ingredient in question or of dietary supplements containing the ingredient.”<sup>27</sup> FDA states that its concern is that any other processing steps may “introduce contaminants, solvents, or impurities whose safety is unknown . . . [or] result in an ingredient that not only differs from the source ingredient but also has an unknown safety profile.”<sup>28</sup>

CHPA acknowledges the Agency’s concerns, but proposes that instead of requiring a consultation for each processing step not included in the Congressional Statement of Agreement, FDA simply identify criteria that can be used by industry in evaluating the effect of potential methodologies on the end product. Such an approach would empower industry to evaluate emerging technologies in an efficient and responsible manner, while ensuring that FDA’s concerns are addressed. Toward this end, CHPA proposes, as examples, the following criteria:

- (1) the process does not introduce contaminants, solvents, or impurities whose safety is unknown, or is of concern, in the concentration or form produced; and
- (2) the physicochemical structure and bioavailability of the dietary ingredient (including synthetic ingredients) remains the same as it is in its food form; and
- (3) use of solvents or other processing aids (*e.g.*, such as those used in botanical extracts or growth media used in probiotic ingredients) should not be limited, allowing for flexibility

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<sup>26</sup> *Id.* at 27 (emphasis added)

<sup>27</sup> *Id.* at 27

<sup>28</sup> *Id.* at 27

in manufacturing processes as long as the end product is safe

Use of these criteria would allow industry to evaluate and adopt technological advances in manufacturing in an efficient manner. In addition, publication of these clear criteria by FDA would increase transparency in dietary supplement regulation, and would enable industry to work with FDA to ensure safety.

The statutory language already incentivizes industry to align with FDA criteria on “chemically altered,” making mandatory consultation unnecessary. Section 413(a) makes clear that a dietary supplement that does not comply with the criteria will risk being “deemed adulterated under section 342(f)” of the FFDCA (emphasis added), subjecting the offending product to FDA enforcement action including seizure, injunction and criminal prosecution.<sup>29</sup> In such cases, FDA does not need to produce “the preponderance of evidence as to harmful effects” from the dietary supplement, the typical Section 402(f) standard. Instead, the Agency can take enforcement action simply by demonstrating that there is chemical alteration contrary to Section 413(a)(1).

Moreover, DSHEA gives FDA multiple additional tools that it could use to take action against a manufacturer who markets a dietary ingredient that has been chemically altered in such a way as to make it unsafe. These provisions were explicitly drafted in order to provide a multi-layered safety net and should be used instead of FDA requiring increasingly burdensome analyses by industry.

As discussed above, FDA can rely on Section 402(f)(1)(A), which states that a dietary supplement is adulterated if it “presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.” Alternatively, Section 402(f) provides FDA with Sections 402(f)(1)(C) or (D), which would allow it to take action against a dietary supplement that is adulterated because it poses an “imminent hazard to public health or safety” or because it contains a dietary ingredient that bears or contains any poisonous or deleterious substance which may render it injurious to health “under the conditions of use recommended or suggested in the labeling.” Bringing forward evidence under any of these sections is the current approach to safety under DSHEA and should be adequate to protect the public health.

## **V. FDA Must Acknowledge Self-Affirmed GRAS Status as a Valid Alternative to NDI Notification**

In the 2011 Draft Guidance, FDA posed the question of whether an NDI notification would be required for “a dietary ingredient that has been listed or affirmed by FDA as generally recognized as safe (GRAS) for direct addition to food, self-affirmed as GRAS for direct addition to food, or approved as a food additive in the U.S.”<sup>30</sup> FDA’s response to this question noted that no NDI notification would be required as long as the direct food additive or

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<sup>29</sup> Federal Food, Drug & Cosmetic Act, Section 301

<sup>30</sup> 2011 FDA Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, July 2011, at IV.B.2

GRAS substance had been used in the food supply and is to be used as an NDI without chemical alteration pursuant to Section 413(a)(1).

The 2016 Draft Guidance poses the same question, but inexplicably deletes the phrase “self-affirmed as GRAS for direct addition to food,” from the question.<sup>31</sup> There is absolutely no legal basis for this change and CHPA urges FDA to quickly correct its omission.

Ingredients that are determined to be GRAS are implicitly recognized as an exception to the food additive category and are exempt from the food additive petition process.<sup>32</sup> The FFDCFA does not prescribe procedures for determining whether an ingredient is GRAS. Manufacturers have always been free to deem foods and food components as GRAS and then go straight to market. This fact was acknowledged most recently in FDA’s final rule, “Substances Generally Recognized as Safe,”<sup>33</sup> (“GRAS Rule”), which finalized the voluntary GRAS Notification process. Therein, FDA changes the nomenclature for GRAS self-affirmations to “independent conclusions” of GRAS status,<sup>34</sup> and confirms that such independent conclusions remain an acceptable route of establishing safety, subject to the same standards as GRAS Notifications.<sup>35</sup>

FDA must extend its recognition that no NDI notification is necessary for GRAS substances that have “been used in the food supply (i.e., in conventional foods)” “without chemical alteration,” to those ingredients that are the subject of “independent conclusions” of GRAS status, as well as those “listed or affirmed by FDA” as GRAS. Just as it does in its GRAS Rule, FDA should make clear that it will accept quality independent conclusions of GRAS status meeting the stated well-articulated criteria for all GRAS determinations in the NDI notification context.

## **VI. FDA Needs to Ensure its Approach to Trade Secrets Supports the NDI Master File Concept in Order to Enhance Consumer Safety**

CHPA commends FDA on the introduction of the NDI Master File concept. However, this system will not work unless FDA also recognizes trade secret protection for applicable safety data. Allowing parties to rely on an NDI Master File established by a previous party has the potential to reduce unnecessary duplicative submissions from ingredient suppliers, dietary supplement manufacturers and distributors. Moreover, the requirement of written authorization for reliance creates a potentially meaningful incentive for NDI notifiers to invest in rigorous safety studies that will be relied upon by others only with their permission.

But in the 2016 Draft Guidance, FDA also states:<sup>36</sup>

You may also submit a confidential “NDI master file” to FDA which contains the manufacturing, specifications and other identity

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<sup>31</sup> 2016 Draft Guidance at 23-24

<sup>32</sup> Federal Food Drug & Cosmetic Act, Section 201(s)

<sup>33</sup> 81 *Fed. Reg.* 54960 (August 17, 2016)

<sup>34</sup> *Id.* at 54984

<sup>35</sup> *Id.* at 55027

<sup>36</sup> 2016 Draft Guidance at 28-29

information needed to completely describe the ingredient. You may incorporate by reference the contents of the master file into an NDI notification. You may also authorize other firms to reference the contents of the master file in notifications describing the ingredient they obtain from you. FDA expects that most submitters will identify the contents of NDI master files and ingredient specifications as trade secrets.

In Section IV.C.5 discussion of the 2016 Draft Guidance,<sup>37</sup> FDA makes clear that reliance on “non-public safety data” in a prior NDI notification master file requires a signed authorization:

[An] NDI notification for [a] new supplement made with NDI-B1 could simply consist of data showing that NDI-B1 is identical to NDI-A1, a reference to the safety evaluation in Supplier A’s notification [for NDI-A1], and a signed authorization from Supplier A for Manufacturer X to use any non-public safety data from A’s notification and the manufacturing master file.”

FDA’s approach addresses the issue that others can also rely on safety data, but this can be a disincentive to undertake expensive safety studies. This disincentive can be overcome if FDA revises its description of confidential trade secret information in Section V.A.16. In the 2016 Draft Guidance, however, that section remains unchanged and states that “[i]nformation about history of use or other safety information related to the NDI or the dietary supplement, including both published and unpublished studies” is generally not trade secret information.<sup>38</sup>

This statement is inconsistent with Section IV.C.5, quoted above, and with 21 CFR 20.61(a), which defines “trade secret” as “any 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.” Safety studies on innovative ingredients provide the data, and thus the basis, on which to develop and potentially market an innovative dietary ingredient. There is no question that such studies require innovation and substantial effort.

Unpublished studies fall within FDA’s definition of trade secret. And treating the content of safety studies as a trade secret would be consistent with FDA’s current practice with regard to New Drug Applications (“NDAs”). After approval of a NDA, the Agency releases summaries of safety and effectiveness data that were not previously disclosed to the public.<sup>39</sup> Critically, the Agency does not regard the non-public safety studies themselves as releasable information.<sup>40</sup>

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<sup>37</sup> *Id.* at 33 (emphasis added)

<sup>38</sup> *Id.* at 52 (emphasis added)

<sup>39</sup> 21 CFR §314.430(e)

<sup>40</sup> *Id.*

CHPA urges FDA to revise Section V.A.16 of the 2016 Draft Guidance to make this clear.

## **VII. FDA Should Take a Consistent Ingredient-Focused Approach to When an NDI Notification Is Necessary**

An ingredient-focused approach to NDI notifications is dictated by the statute. CHPA therefore asks FDA to revise the 2016 Draft Guidance to remove the requirement that a supplement that combines “the [already-notified] NDI with other dietary ingredients” be the subject of an additional NDI notification. This requirement is simply inconsistent with the statutory language and with FDA’s overall ingredient-focused approach.

### **A. An Ingredient-Focused Approach Supports Dietary Supplement Safety**

FDA’s ingredient-focused approach for NDI notifications is mandated by the plain language of Section 413(a) which is focused on the safety of the new dietary *ingredient*. The sole requirement is that FDA receives adequate information on which *any* party may rely to conclude that its NDI-containing dietary supplement is reasonably expected to be safe. Section 413(a)(emphasis added) states:

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title unless it meets one of the following requirements:

- (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
- (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient **or** dietary supplement provides the Secretary with information . . . which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA correctly interprets these provisions to mean that an additional NDI notification is required for each variant of a dietary ingredient not covered in a prior NDI notification. As articulated in the 2016 Draft Guidance, the requirement for additional NDI notifications extends to conditions of use for the dietary ingredient not covered in the initial NDI notification by a single manufacturer/distributor. In addition, the NDI notification requirement extends to each distinct manufacturer or distributor of a supplement containing the new dietary *ingredient*.

Thus, FDA presents Scenario 1 in which Manufacturer X intends to market a single-ingredient dietary supplement containing “NDI-B1” that purports to contain the same dietary ingredient as “NDI-A1,” which was the subject of an NDI notification by Supplier A. FDA states that “Manufacturer X should submit an NDI notification for the use of NDI-B1 in its single-ingredient dietary supplement because Supplier B has submitted no NDI notification for NDI-B1.”<sup>41</sup> However, if Manufacturer X can establish that the ingredient is the same and that the conditions of use are covered in the previous notification, the NDI notification for the new supplement could consist of data demonstrating that the ingredients are identical, a reference to safety information contained in the original notification and a signed authorization from the original supplier to use any non-public data. If Manufacturer X cannot establish that the ingredient is the same as the ingredient in the prior notification, then a new NDI would be required.

CHPA believes that this ingredient-focused approach helps to ensure that all entities purporting to market a dietary supplement with the NDI are actually using the same ingredient and serves the important purpose of providing FDA with an accurate record of entities marketing NDIs.

Information provided to FDA in NDI notifications can enable the Agency to mobilize the DSHEA safety provisions more effectively. If, for example, safety issues come to light regarding a particular dietary ingredient, FDA would be able to determine whether the issue is tied to a particular manufacturer’s version of the ingredient, reflecting a potential contamination issue, or is linked to the safety of the dietary ingredient more broadly. The Agency could take action under Section 402(f) or (g), as it deems appropriate.

## **B. A Supplement-Focused Approach to Combinations of Already-Notified NDIs Is Limiting and Inconsistent with Congressional Intent**

While an ingredient-focused approach to NDIs makes sense, FDA’s supplement-focused approach to dietary supplements containing already-notified NDIs is limiting and not reflective of Congressional intent. This supplement-focused approach is inconsistent with FDA policy, unnecessary to ensure safety and potentially burdensome to FDA and industry.

In the 2016 Draft Guidance, FDA takes the position that the addition of one dietary ingredient to another creates a *de facto* NDI, which must itself be the subject of a notification:<sup>42</sup>

When dietary ingredients are combined, they can interact. In some cases, these interactions can present risks to consumers. . . . To have a basis to conclude that a dietary supplement that combines an NDI with one or more pre-DSHEA dietary ingredients will reasonably be expected to be safe, it is necessary to consider whether the addition of the other dietary ingredients will affect the safety of the NDI or the resulting dietary supplement.

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<sup>41</sup> 2016 Draft Guidance at 33

<sup>42</sup> *Id.* at 30, 35 (emphasis added)

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A combination of two NDIs is itself an NDI. Although the notifications included in-depth discussions of the safety of the extracts, each of the plants is known to contain glycosides with potent cardiotoxic activity and it is difficult to predict the toxicity of the combination. The new notification should include a discussion of the safety of the combination, . . . in a notification for a combination of two NDIs with no specific safety problems where each of the NDIs had been the subject of a prior notification to FDA that was acknowledged without objection, the section of the new notification discussing the safety of the combination could be brief.

However, there is nothing in the statute or the legislative history to support this view. In fact, Congress specifically rejected this approach in drafting DSHEA. In explaining its addition of Section 402(f) to explicitly establish the grounds on which FDA may deem a dietary supplement adulterated, the Senate Report on DSHEA makes clear that it rejects FDA's prior efforts to require repetitive new safety assessments of already-evaluated ingredients:<sup>43</sup>

FDA contends that each additive ingredient in a multi-ingredient product is a potential food additive with respect to the other ingredients. The FDA therefore deems a multi-ingredient dietary supplement to contain a food additive, even though the supplement consists solely of ingredients that may be sold separately as individual dietary supplements, and no one of which is added to the supplement because of its effect on any other ingredient. As the court observed in the Traco case, under this approach, "it would seem, even the addition of water to food would make the food [water?] a food additive." 984 F.2d at 819.

The Senate Report<sup>44</sup> goes on to reject this approach:

In the committee's judgment, the FDA has disregarded the congressional intent underlying the law regulating food and food additives . . . the FDA has attempted to twist the statute in what the Committee sees as a result-oriented effort to impede the manufacture and sale of dietary supplements.

The Senate Report concludes this discussion by making clear that the safety of combinations of ingredients is instead to be ensured by DSHEA's addition of Section 402(f)(1)(A), (1)(C) and (1)(D).<sup>45</sup>

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<sup>43</sup> Senate Report No. 103-410 (1994) at 14

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

Consistent with this discussion, there is nothing in DSHEA to suggest that the addition of one NDI to a dietary supplement containing another already-notified NDI or grandfathered ingredient necessitates a new notification.

Moreover, the burden of requiring additional NDI notifications for every combination that includes an already-notified NDI is potentially overwhelming. As examples, under this scenario, NDI notifications would be required for minor modifications such as a change in product flavoring or when changing to an excipient containing slightly different incidental components. FDA has estimated that as of 2012 there were 55,600 dietary supplement products on the market, and that 5,560 new dietary supplement products come on the market each year.<sup>46</sup>

There is a possibility that each of these 5,560 new dietary supplement products could contain an already-notified NDI in combination with another already-notified NDI or grandfathered ingredient. As such, the Agency could be the recipient of up to 5,560 additional NDI notifications per year. The expectation of numerous NDI notifications for combinations of already-notified NDIs is inconsistent with FDA's current estimate that it will receive 55 NDI notifications per year.<sup>47</sup> If FDA did receive significantly more notifications than expected, it would quickly be overwhelmed.

The repeat notification requirement would also stand as a significant burden for industry. FDA has previously estimated that an NDI notification would require only 20 hours to complete,<sup>48</sup> a figure that FDA itself has acknowledged fails to take into account the recommendations in either the 2011 Draft Guidance or 2016 Draft Guidance.<sup>49</sup> Even using this low number, the person hours required for multiple additional NDI notifications quickly add up and can become burdensome for small companies. The added time and expense would stand in the way of the industry's ongoing innovation and contravene Congress's admonition that "the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products . . . to consumers."<sup>50</sup>

There is simply no safety benefit to match this burden. Any party marketing a product containing a combination of ingredients is subject to the safety standards in Section 402(f), drafted specifically to provide multiple layers of safety assurance. Under Section 402(f)(1)(A), a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of

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<sup>46</sup> 2016 Draft Guidance at 12

<sup>47</sup> "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient," 80 Fed. Reg. 10121, 10122 (Feb. 25, 2015).

<sup>48</sup> "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient," 76 Fed. Reg. 51986, 51987 (Aug. 19, 2011).

<sup>49</sup> "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient," 80 Fed. Reg. at 10122 ("After publishing a revised draft guidance on NDINs and related issues, we intend to publish a 60-day notice inviting comment on the proposed collections of information associated with that document. At that time, we will carefully evaluate all comments we receive.")

<sup>50</sup> Pub L. No. 103-417, Section 2(13)

use.” Section 402(f)(1)(C) allows FDA to take action against a dietary supplement that is adulterated because it poses an “imminent hazard to public health or safety.” Section 402(f)(1)(D) further provides that a dietary supplement is adulterated if it contains a dietary ingredient that bears or contains any poisonous or deleterious substance which may render it injurious to health “under conditions of use recommended or suggested in the labeling.” FDA is authorized to take enforcement action under any of these provisions where it has evidence of a safety issue and FDA, not industry, bears the burden of proof. Therefore, repeat notifications are simply unnecessary.

We appreciate the opportunity to submit these comments and look forward to working with the Agency to develop clear and consistent guidelines regarding implementation of the NDI notification process. Please feel free to contact us should you have any questions or require additional information.

Respectfully submitted,



Jay Sirois, Ph.D.  
Director, Regulatory & Scientific Affairs  
Consumer Healthcare Products Association



Scott Bass, Counsel  
Sidley Austin, LLP



Emily Marden, Counsel  
Sidley Austin, LLP