U.S. Government Accountability Office

# Prenatal Supplements: Amounts of Some Key Nutrients Differed from Product Labels

GAO-24-106689
Q&A Report to the Chair, Subcommittee on Human Rights and the Law, Committee on the Judiciary, U.S. Senate

December 12, 2023

## Why This Matters

Many pregnant Americans take prenatal supplements to promote parental and fetal health as soon as they know they are pregnant. Spending on prenatal supplements in the U.S. market is projected to be over $189 million by the end of 2023 and is expected to grow.[1] The Food and Drug Administration (FDA) regulates dietary supplements—including prenatal supplements—as a special category of food. Therefore, unlike drugs, dietary supplements are subject to a limited pre-market approval process. As a result, FDA may not discover mislabeling and contamination until after the products are on the market.

We were asked to assess the accuracy of over-the-counter prenatal supplement labels for amounts of certain nutrients—vitamins and minerals—and determine whether the supplements also contain harmful substances, such as heavy metals. We contracted with an accredited laboratory to conduct testing. This report describes the accuracy of labels for amounts of tested nutrients and possible contaminants in selected best-selling prenatal supplements based on the laboratory testing. It also provides information on FDA's role overseeing prenatal supplements and describes what consumers need to know about prenatal supplements and labels. For all data and results, see GAO-24-107042.

## Key Takeaways

- Eleven of the 12 prenatal supplement products we tested contained at least one tested nutrient with an average amount outside acceptable deviations from the label value. One product had an average amount of folic acid that may cause health concerns based on metrics from the Institute of Medicine.
- None of the prenatal supplement products we tested contained selected heavy metal contaminants at concentrations likely to be a health concern based on metrics used by FDA.
- Prenatal supplements are not a substitute for a healthy diet but can help meet the nutritional needs of the fetus and pregnant individual.
- FDA lacks the authority to regulate dietary supplements—including prenatal supplements—with the same rigor as drugs, and oversight primarily occurs once the supplements are already on the market.
- We recommend that Congress consider measures for allowing FDA sufficient authority to carry out its oversight of dietary supplements. FDA agreed with this matter.

## What are prenatal supplements?

When paired with a healthy diet, prenatal supplements can help the average American obtain sufficient nutrients to support a healthy pregnancy.[2] During pregnancy, the fetus and placenta divert nutrients from the parent's blood. To account for this, the recommended dietary allowance of certain nutrients for pregnant individuals is higher than for non-pregnant individuals. For example, the recommended dietary allowance of 18 milligrams per day of iron increases to 27 milligrams per day during pregnancy.

Although pregnant Americans generally have a higher-quality diet than other Americans, they are still not meeting recommendations for nutrient intake, according to the Dietary Guidelines for Americans, a joint report from the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services. Experts we spoke with from the American College of Obstetricians and Gynecologists (ACOG) agreed that while it is possible to obtain the necessary nutrients through diet alone, prenatal supplements are currently necessary for adequate nutrient consumption during pregnancy based on an average American's nutritional habits.

Prenatal supplements can help individuals who may not have the ability to obtain the appropriate nutrients from diet alone. Factors including the pregnant individual's current diet, medical history, and food access can contribute to their ability to obtain appropriate amounts of some nutrients, according to experts. For example, a vegan or vegetarian diet may not provide the most absorbable forms of certain nutrients, like vitamin A or iron. Furthermore, individuals residing in an area with food access issues may also not be able to obtain a sufficient amount of key nutrients. FDA guidance advises that consumers talk to their health care professional before deciding to purchase or use prenatal supplements.[3]

Supplements can come in different forms—such as gummies (also called chewable gels), softgels (a type of capsule), or tablets—which often affect what nutrients can be incorporated into the supplement and how easily those nutrients can be delivered to and absorbed by the body. Some stakeholders and experts we interviewed, including USDA officials, expressed concerns about prenatal gummies. For example, some multivitamin gummies do not contain iron and therefore may not be the best prenatal supplement for an individual prone to anemia. On the other hand, experts from ACOG stated that compliance can be a challenge, as many patients find prenatal supplement pills large, foul tasting, and hard to swallow. This can be particularly true for pregnant patients who are already experiencing nausea, especially in the first trimester, when many of the nutrients are critical for fetal development. A gummy form, therefore, may be preferable for some patients, even if it does not provide the ideal amounts of some nutrients.

While prenatal supplements can be beneficial, no federal statutory definition exists for what a prenatal supplement is and what these products should contain. This has resulted in a large and highly variable market. According to experts from ACOG, many patients assume all prenatal supplements contain the same nutrients and have all of the nutrients that are important for pregnancy, and thus may not closely examine the label. As a result, consumers may select a product that does not contain the nutrients they need to supplement their diet. For example, not all prenatal supplements contain iodine—an essential nutrient at

risk of deficiency or insufficiency for many Americans, according to experts. Additionally, not all forms of an ingredient have the same effects or ability to be absorbed. For example, folate can be present in a supplement in the form of folic acid, folate, or methylfolate. However, according to the Centers for Disease Control and Prevention (CDC) website, folic acid is the only form of folate shown to help prevent neural tube defects. For more information on what to look for when reading a prenatal supplement label, please refer to figure 5 in appendix I.

FDA is responsible for overseeing dietary supplements as a special category of food, which means that supplements, unlike drugs, are generally not required to be evaluated for quality or safety pre-market. Under this regulatory approach, it is possible for supplements to reach the market with amounts of nutrients that do not match the amounts on the label or containing potentially harmful substances, such as heavy metals.

## Did the amounts of nutrients in the prenatal supplements we tested match the amounts stated on the labels?

Based on laboratory testing conducted in July and August 2023, we found that almost all (11 of 12) of the tested prenatal supplement products had average quantities of at least one tested nutrient that were outside acceptable deviations from the label. This could lead to a pregnant individual either consuming too much or too little of key nutrients. Below we explain why we tested for six specific nutrients, the test results, and possible effects on an individual's health and pregnancy.

### Selected nutrients

We organized our analysis of six laboratory-tested nutrients into two groups: three key nutrients recommended by experts and in literature for beneficial pregnancy outcomes—folic acid, iodine, and iron—and three nutrients recommended in small doses but with harmful effects to a pregnancy if doses are too high or in certain combinations—vitamins A, C, and E. See tables 1 and 2 for more information on the nutrients in these groups.

**Table 1. Key Nutrients Recommended by Experts for Prenatal Supplements**

| | Folic acid[a] | Iron | Iodine |
|---|---|---|---|
| **Benefits** | Prevents neural tube defects—defects in the fetus's brain and spine | Reduces the risk of parental anemia | Essential component of thyroid hormones, which are necessary for brain development<br>Supplementation reduces risk of thyroid disorders in parent and fetus |
| **Effects of deficiency** | Neural tube defects in the fetus and possible parental anemia | Parental anemia—associated with increased risks of parental, fetal, and neonatal mortality, and low birthweight | Impaired neurodevelopment of the fetus, possible miscarriage, stillbirth, and infant mortality |
| **Daily value for pregnant or lactating individuals[b]** | 600 micrograms DFE[c] | 27 milligrams | 290 micrograms |
| **U.S. Pharmacopeia acceptable thresholds for nutrient relative to label** | Softgels and tablets: 100 to 150 percent<br>Gummies: 100 to 245 percent | Softgels and tablets: 100 to 125 percent<br>Gummies: not defined | Softgels, tablets, and gummies: 100 to 160 percent |
| **Tolerable upper intake level[d]** | 1000 micrograms/day[e] | 45 milligrams/day | 1,100 micrograms/day |

Source: GAO analysis of literature | GAO-24-106689

[a]Folic acid is a synthetic form of vitamin B9 that is converted to folate in the body and is more easily absorbed than folate.

[b]The Food and Drug Administration establishes daily values.

[c]DFE, or dietary folate equivalent, is a unit of measurement used because folic acid is more easily absorbed by a person's body than other forms of folate.

[d]The Institute of Medicine defined these tolerable upper intake levels as the maximum daily dose unlikely to cause adverse side effects in the general population.

[e]The tolerable upper intake level only applies to synthetic forms of folate that are obtained from dietary supplements, fortified foods, or a combination of the two.

**Table 2. Vitamins That Pose Risks When Used in High Doses in Prenatal Supplements**

| | Vitamin A[a] | Vitamin C | Vitamin E |
|---|---|---|---|
| **Benefits** | Plays a role in the growth of most cells and organs, including the eyes, heart, and lungs | Helps maintain strong bones and teeth and can help the body absorb iron from plant sources | Antioxidant |
| **Effects of deficiency** | Parental anemia, night blindness | Scurvy, possible role in pre-eclampsia and anemia | Possible role in pre-eclampsia and fetal defects |
| **Daily value for pregnant or lactating individuals[b]** | 1,300 micrograms RAE[c] | 120 milligrams | 19 milligrams |
| **U.S. Pharmacopeia acceptable thresholds for nutrient relative to label** | Softgels and tablets: 100 to 165 percent<br>Gummies: 100 to 170 percent | Softgels and tablets: 100 to 150 percent<br>Gummies: 100 to 250 percent | Softgels and tablets: 100 to 165 percent<br>Gummies: 100 to 170 percent |
| **Tolerable upper intake level[d]** | Pre-formed vitamin A: 3,000 micrograms/day<br>Beta-carotene: none | 2,000 milligrams/day | 1,000 milligrams/day[e] |
| **Concerns** | Extremely high levels of pre-formed vitamin A intake (>7,500 micrograms RAE) within 60 days of conception have been associated with miscarriage and toxicity to the fetus[f] | When there is >1,000 mg of vitamin C with >400 IU[g] vitamin E, there is an increased risk of abdominal pain during pregnancy, premature rupture of membrane, and fetal loss or neonatal death[f] | |

Source: GAO analysis of literature | GAO-24-106689

[a]Vitamin A can be present in prenatal supplements in two forms: pre-formed vitamin A (e.g., retinol or retinyl palmitate) and pro-vitamin A carotenoids (e.g., beta-carotene). While only pre-formed vitamin A is associated with toxic effects at high doses, carotenoids alone are insufficient to maintain normal levels of vitamin A.

[b]The Food and Drug Administration (FDA) establishes daily values.

[C]RAE is retinol activity equivalents, a unit used due to the fact that different forms of vitamin A (e.g., pre-formed vitamin A versus beta-carotene) are absorbed by a person's body at different rates.

[d]The Institute of Medicine defined these tolerable upper intake levels as the maximum daily dose unlikely to cause adverse side effects in the general population.

[e]The tolerable upper intake level only applies to the synthetic forms of vitamin E that are obtained from dietary supplements, fortified foods, or a combination of the two.

[f]World Health Organization, "WHO recommendations on antenatal care for a positive pregnancy experience," 2016.

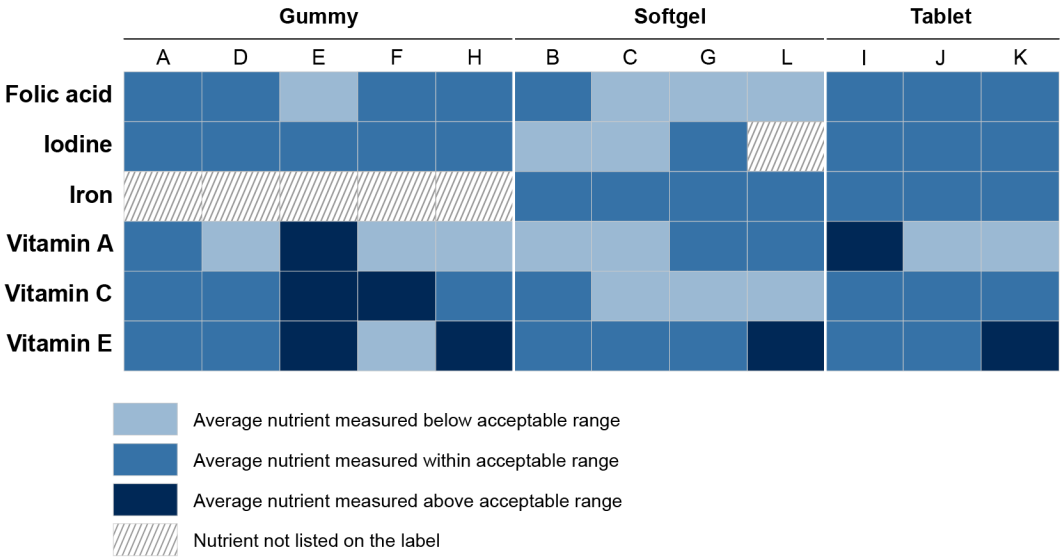
[g]IU stands for international units and was the unit for labeling vitamin E prior to 2016. FDA has guidance on how to convert IU to milligram quantities based on whether vitamin E is present in a natural or synthetic form. (FDA, "Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels: Guidance for Industry" 2019.)

## Test results and discussion

We found that 11 of the 12 prenatal supplements had at least one tested nutrient with an average quantity present outside the U.S. Pharmacopeia (USP) thresholds for deviation from the label value. For four of the 12 prenatal supplements, we found that the majority of the tested nutrients were outside the USP thresholds (see fig. 1, products C, E, F, and L). We submitted three different lots of each supplement product to the laboratory for testing. When we report an average quantity, we are referring to the average across the lots of each supplement product tested. Figure 1 shows how the average measured nutrient

quantity for each supplement product compared to the USP thresholds. For a full description of the results by lot, see GAO-24-107042.

**Figure 1: Average Measured Amount of Tested Nutrients Compared to Acceptable Ranges of Deviation from the Label Value in Selected Prenatal Supplements**



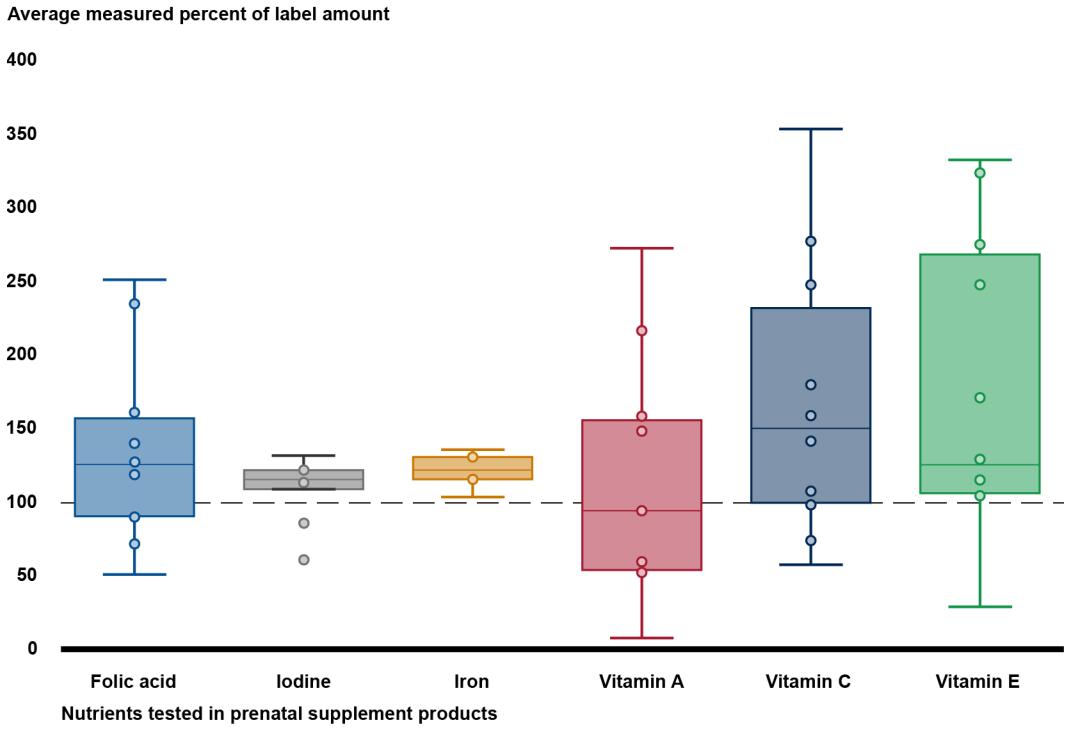

Source: GAO. | GAO-24-106689

Note: "Acceptable range" is based on Food and Drug Administration (FDA) requirements that a nutrient must not be lower than the value on the label and U.S. Pharmacopeia (USP) upper thresholds for nutrients in specific forms. USP upper thresholds are voluntary manufacturing guidelines and are not required for supplements. The letters A–L are anonymizing identifiers for each of the 12 tested supplement products.

We used USP-developed thresholds as a metric to determine acceptable deviations between the average measured contents and the label value for each nutrient. The USP thresholds are manufacturing guidelines for how much a nutrient in a multivitamin—such as a prenatal supplement—can deviate from the stated amount for the nutrient on the label. USP thresholds represent a percentage of the amount listed on the label and are not the same as the percent of daily value listed on the label. These thresholds vary based on the nutrient and on the dietary supplement form—gummy, softgel, and tablet (see tables 1 and 2). Manufacturers are not required to conform to USP thresholds unless their products' labels state that the products comply with USP standards. However, USDA officials stated that most manufacturers use USP's thresholds.[4] In most instances, the conclusions for the average matched the conclusions for at least two of the three individual lots of that product. See the technical supplemental material GAO-24-107042 for more specific results and comparative analysis.

**Overall themes.** Most nutrients, on average, were present in the tested prenatal supplements in amounts equal to or higher than the label amount. However, only eight were above the upper USP acceptable threshold (dark blue, see fig. 1). There were 17 instances in which an average nutrient amount was below the lower USP acceptable threshold (light blue, see fig.1). There was also more variability for the supplements tested in the average measured percents of label amount of vitamins compared to minerals, which could be attributed to the lower stability of certain vitamins in supplement form (see fig 2.).

**Figure 2: Average Measured Percentages of Label Amount across Prenatal Supplement Products Tested**

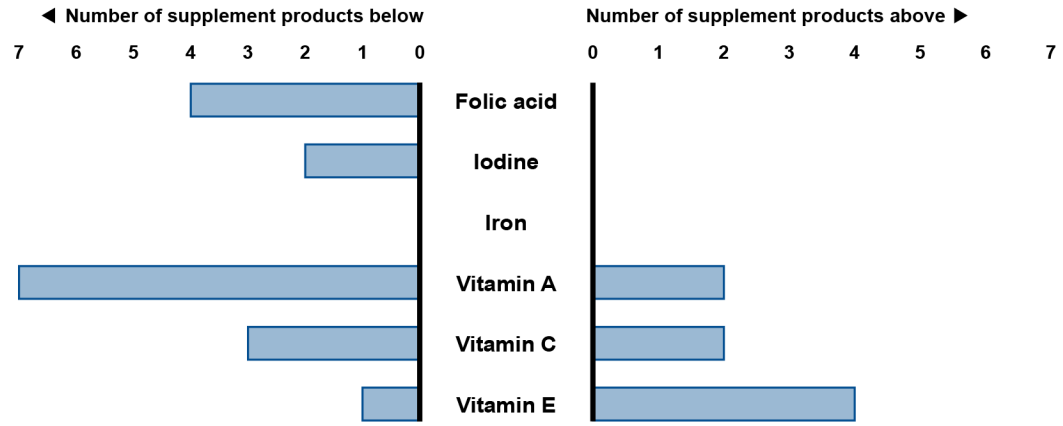



Source: GAO. | GAO-24-106689

Note: Iron was only present in tablet and softgel forms, and one softgel sample did not have iodine on the label. This is a box and whisker plot, which displays variation in the data. The "box" represents the middle 50 percent of the data, and the inner horizontal line represents the median value. The "whiskers" represent the variation in the data outside the middle 50 percent. The circles represent individual data points, and any data points outside of the box and whisker plot for the nutrient are considered outliers.

**Folic acid, iodine, and iron.** The three key nutrients we tested that are recommended by experts and in literature for prenatal supplementation—folic acid, iodine, and iron—most frequently matched the label amounts (see fig. 3). However, four supplement products had average folic acid levels below the amount on their labels (i.e., they contained 91, 89, 71, and 50 percent of the amount on the label). Two supplement products had average iodine levels more than 10 percent below the amounts on their labels. Taking a supplement that has a folic acid or iodine value lower than the amount on the label could result in an individual not receiving the full benefit of these nutrients in preventing birth defects. All supplement products had average iron levels within acceptable deviations, which is consistent with what we heard from USDA officials about minerals, such as iron, tending to be present at close to the labeled level.

**Figure 3: Number of the 12 Selected Prenatal Supplement Products with Average Tested Nutrient Values Above or Below U.S. Pharmacopeia Thresholds**




Source: GAO. | GAO-24-106689

Note: While supplements cannot have class I nutrients below 100 percent of the amount stated on the label, the upper U.S. Pharmacopeia thresholds are voluntary manufacturing guidelines and are not required for supplements.

We found that all three lots of product K and one lot of product B contained an amount of folic acid above the tolerable upper intake level, though not above the USP threshold. Because USP thresholds are manufacturing guidelines and not metrics of safety, we used the tolerable upper intake levels for vitamins and minerals established by the Institute of Medicine—now the National Academy of Medicine—as a safety benchmark.[5] A tolerable upper intake level is the maximum daily dose unlikely to cause adverse side effects in the general population. According to a National Institutes of Health (NIH) fact sheet for folate, excessive amounts of folic acid intake from dietary supplements may mask the measurement of an underlying vitamin B12 deficiency.[6] There is also some evidence that an intake of folic acid above the tolerable upper intake level may negatively affect fetal cognitive development, according to NIH officials.

**Vitamins A, C, and E.** The three nutrients that may have concerns at high levels or in certain combinations—vitamins A, C, and E—were the most variable in measured amounts compared to the label amounts (see fig. 2), but none exceeded their respective tolerable upper intake levels. Vitamin E showed the greatest inconsistency, with the different supplement products A through L with an average amount of vitamin E anywhere from 28 to 332 percent of what was stated on the label. Vitamin A was most frequently outside the acceptable deviations from the amount stated on the label, affecting nine of the 12 supplement products (see fig. 3). However, most (seven of the nine) were below the amount stated on their label rather than over. While two of those seven were, on average, 93 percent of the label amount, the other five were 59 percent or less.[7] Not taking enough of these nutrients may result in the deficiency effects listed in table 2, but experts noted that more research is needed to understand whether these nutrients are necessary for beneficial pregnancy outcomes.

While none of the vitamin A samples on average were above the tolerable upper intake level, we did find that one individual lot of product E was slightly over this level. However, the measured amount in the product did not exceed 7,500 micrograms retinol activity equivalents (RAE)—the amount above which a single dose may result in congenital birth defects if taken within the first 60 days of

pregnancy, according to the World Health Organization (see table 2). Therefore, this level of vitamin A in this individual product is not likely to be a health risk.

## Did the prenatal supplements we tested contain any heavy metal contaminants?

Based on laboratory testing conducted in July and August 2023, we found trace amounts of heavy metals in half of the prenatal supplement products (six of 12), but not amounts likely to cause a health concern based on metrics used by FDA. The heavy metals we tested—lead, arsenic, cadmium, and mercury—occur naturally in low levels in the environment, and therefore may be present in supplement ingredients. Below we discuss why we tested for certain heavy metals, what we found, and the health implications of those findings.

### Selected heavy metal contaminants

We tested for lead, arsenic, cadmium, and mercury because they have all been associated with harmful effects on the fetal brain, cognitive development, and growth. With respect to oversight of the safety of prenatal supplements, one of FDA's top priorities is reducing exposure to each of these four heavy metals in these products.[8] See table 3 for more details about the exposure limits and risks associated with each of these heavy metals.

**Table 3. Fetal Health Risks Associated with Heavy Metal Contaminants**

| | Lead | Arsenic | Cadmium | Mercury |
|---|---|---|---|---|
| **Daily exposure limit**[a] | 8.8 micrograms[b] | 0.3 micrograms per kilogram of body weight[c] | 0.21 –0.36 micrograms per kilogram of body weight[d] | 0.57 micrograms per kilogram of body weight[c] |
| **Risk** | Neurodevelopmental disorders, greater risk of premature delivery and impaired fetal growth | Impaired neurodevelopment and fetal growth, possible increased risk of infections | Impaired neurodevelopment | Impaired neurodevelopment and harmful to the nervous system |

Source: GAO analysis of literature | GAO-24-106689

[a]The Food and Drug Administration (FDA) uses these values as benchmarks to determine whether the amount of a contaminant found in a food or supplement is a potential health concern.

[b]FDA set this limit for individuals of a childbearing age. (Brenna M. Flannery and Karlyn B. Middleton "Updated interim reference levels for dietary lead to support FDA's Closer to Zero action plan," *Regulatory Toxicology and Pharmacology,* vol. 133 (2022): 105202.)

[c]FDA used this toxicological reference value in previous work on the presence of heavy metal contaminants in prescription prenatal supplements. (Fong Sam, J.; Andrews, K; Kuszak, A. "Toxic Elements in Prescription Prenatal Supplements" Presented at the Winter Conference on Plasma Spectrochemistry, Tucson, AZ, January 13-18, 2020.)

[d]FDA established this oral toxicological reference value in a recent publication. (Heather R. Schaefer et al., "Reassessment of the cadmium toxicological reference value for use in human health assessments of food," *Regulatory Toxicology and Pharmacology,* vol. 144 (2023): 105487.)

### Test results and discussion

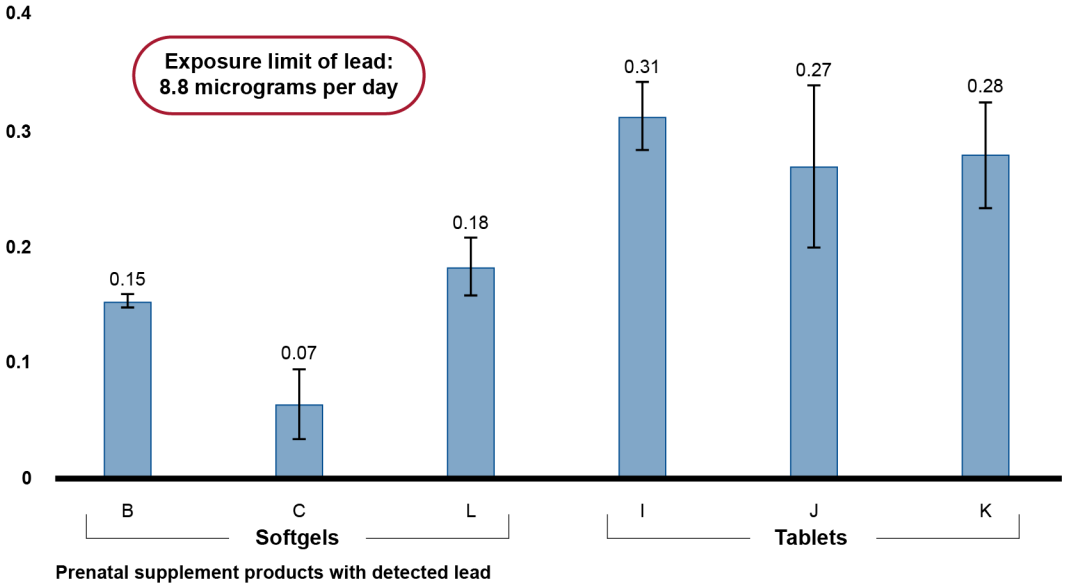
Testing identified heavy metal contaminants in six of the 12 prenatal supplement products tested, but all concentrations were low and unlikely to pose a health concern based on daily exposure limits used by FDA. All six products had trace amounts of lead, and two of these six products also contained trace amounts of cadmium. Lead and cadmium were otherwise below the detection limits in all other samples. Likewise, arsenic and mercury were below the detection limits in all the samples.

Being below the detection limit does not necessarily mean there is no amount of those metals present in the products. Rather, it means that any amount of those metals that may be present is extremely small and unlikely to be a health concern. Our findings from the testing align with a previous study that FDA

conducted on prescription prenatal supplements, in which lead was the most commonly detected heavy metal of the four, and all detected heavy metals were at levels that were determined not likely to pose a health concern.[9]

Figure 4 shows that three of the four softgels and all three of the tablets contained detectable amounts of lead. None of the gummies contained detectable amounts of lead. The highest average lead content found was 0.31 micrograms per daily serving, which is well below FDA's threshold of 8.8 micrograms of lead per day for individuals of a childbearing age. While FDA recognizes that a safe level of lead exposure has not been identified for fetal brain and cognitive development, based on existing data and other information, FDA concluded that the levels found in its study—including an average lead value of 0.59 micrograms per daily serving— were unlikely to pose a health concern.

**Figure 4: Average Amounts of Detectable Lead Found in Prenatal Supplement Products**




Source: GAO. | GAO-24-106689

Notes: We only show products that had detectable amounts of lead. Error bars show one standard deviation above and below the average calculated for three samples of each product. A larger standard deviation (longer error bar) means there was more variance in the measured contaminant level across lots. The letters A–L are anonymizing identifiers for each of the 12 tested supplement products. Lead was below the detection limit in two of the three samples of product C, and so half of the detection limit were used as placeholder values for calculating the average and standard deviation.

Two of the lead-containing products also had detectable amounts of cadmium. One of these products was a softgel (0.52 ± 0.02 micrograms per daily serving) and one was a tablet (0.32 ± 0.02 micrograms per daily serving). FDA uses a daily exposure limit of 0.21–0.36 micrograms of cadmium per kilogram of body weight per day for any individual; this corresponds to a limit of 14.3–24.5 micrograms per day for a 150-pound individual. Based on daily exposure limits used by FDA, neither of these findings of cadmium is likely to pose a health concern.

Federal laws and regulations do not define daily exposure limits for lead, cadmium, arsenic, or mercury in dietary supplements, including prenatal supplements. Rather, manufacturers are required to establish acceptable contamination limits to prevent introducing contaminated products to the market

as a part of current good manufacturing practices—systems that ensure proper design, monitoring, and control of manufacturing processes and facilities—described in federal regulations.[10] FDA made its determinations on whether amounts of heavy metals were likely to pose a health concern in its 2020 study based on available toxicological data from other expert groups, including the Environmental Protection Agency (EPA). According to FDA, the daily exposure limits presented above in table 3 do not establish a permissible level of contamination.

The presence of heavy metals may not be from the manufacturing process, but rather the ingredients chosen for the vitamins or minerals they contain. For example, bioaccumulation—a build-up of environmental substances in an organism—can result in an increased presence of arsenic in rice (e.g., a source of iron and calcium) and mercury in fish (e.g., a source of omega-3 fatty acids). Additionally, research shows a correlation between calcium and lead in naturally occurring sources of calcium such as shells, bone, and rock.

## How does FDA provide oversight of prenatal supplements?

The oversight of prenatal supplements—a subset of dietary supplements—falls under FDA's responsibility for overseeing dietary supplements.[11] FDA regulates dietary supplements under the Federal Food, Drug, and Cosmetic Act,[12] including amendments made by the Dietary Supplement Health and Education Act of 1994 (DSHEA).[13] While dietary supplements are defined in federal law,[14] there is no federal statutory definition specific to prenatal supplements. As a result, prenatal supplements fall under the general category of dietary supplements, which DSHEA lists as a special category of food. Therefore, we use dietary supplements to frame the discussion of prenatal supplements.

FDA regulates over-the-counter and prescription prenatal supplements the same, according to agency officials. Therefore, generally neither type is required to be evaluated for effectiveness or safety pre-market, but both are held to the standards of quality outlined in the current federal good manufacturing practices regulations. Below is a brief discussion of FDA's oversight and enforcement roles for dietary supplements (see GAO-17-416 for additional detail).[15]

**Post-market oversight.** While some drugs—such as certain over-the-counter aspirin products—require testing for safety and efficacy before sale on the market, dietary supplements generally do not. This is because FDA does not generally have authority under the Federal Food, Drug, and Cosmetic Act, as amended, to require pre-market testing for dietary supplements. As a result, FDA's oversight of prenatal supplements is almost entirely post-market, according to officials.[16] Once a product is on the shelves, FDA monitors dietary supplement manufacturers, distributors, or packers—referred to as firms—for potential safety or quality concerns. FDA primarily relies on post-market monitoring—including reviewing complaints or reports of health problems or adverse events it receives from industry, health care practitioners, and consumers, and conducting inspections of dietary supplement firms. These monitoring activities may result in enforcement actions and related outreach.[17]

FDA also reviews dietary supplement labels post-market. FDA regulations require that dietary supplement labels include a statement that classifies the

product as a supplement, a list of all ingredients, and the quantity of ingredients present in significant amounts in the product.[18] If FDA finds inaccurate claims on the label or finds that the label does not accurately reflect the contents of the dietary supplement, the agency deems the supplement misbranded and can take enforcement action.[19]

FDA regulations require labels to include the firm's name and a domestic phone number or address for individuals to submit an adverse event report to the firm. According to FDA officials, this helps the agency identify and act on public health issues associated with the use of dietary supplements because firms are required to notify FDA of any serious adverse event report they receive.[20] Adverse events—such as health-related reactions or illnesses—also can be reported by anyone directly to FDA through the agency's Safety Reporting Portal.[21] According to FDA's FAQ on the portal, all reports received through this portal are reviewed and, depending on the seriousness of the issue, will either be investigated immediately or designated for other action.

FDA inspects firms for compliance with current good manufacturing practice regulations and conducts follow-up inspections as a method of post-market oversight. [22] There are four general types of inspections: (1) routine surveillance, (2) consumer complaint investigations, (3) for-cause compliance inspections, and (4) follow-up to a regulatory action. According to FDA officials, surveillance activities may include product examinations, sampling, and testing. For example, FDA may test a dietary supplement to determine whether it is contaminated with substances such as heavy metals.

**Enforcement actions**. Once FDA identifies a concern in any area discussed above, it may take enforcement action against a firm through advisory and regulatory actions. Advisory actions—such as sending a warning letter—notify firms that FDA has found the firm noncompliant. According to FDA officials, firms can voluntarily come into compliance before the agency takes further action. Regulatory actions are more serious than advisory actions. Among the regulatory actions available to FDA are administrative enforcement tools—such as issuing a mandatory recall—or judicial court actions—such as filing a seizure action against products that are contaminated, misbranded, or otherwise in violation of federal law.[23]

According to agency-provided data on fiscal year 2022 enforcement actions, FDA inspected 517 dietary supplement firms, analyzed 686 samples of dietary supplements including 17 prenatal supplements, issued 37 warning letters, and took three regulatory actions against dietary supplement firms.[24] Additionally, FDA reviewed certain import information for dietary supplements—including prenatal supplements.[25]

## How does the dietary supplement industry regulate itself?

The dietary supplement industry has mechanisms for self-regulation, such as trade associations that require members to adhere to additional standards of quality and third-party verification (or certification) of products. Organizations offering third-party product verification or certification may differ in their requirements and standards but offer independent testing of dietary supplements to ensure the contents match the label and do not contain harmful contaminants. According to officials from both verification organizations we spoke with, dietary

supplement firms may choose to have their products verified for a variety of reasons, such as providing assurances to their customers about what is in the product. Moreover, some retailers require proof that products underwent certain testing before they can be sold. Both organizations we spoke with also provide or verify third-party inspection of the manufacturing facility to ensure compliance with current good manufacturing practice regulations.

Officials from both verification organizations we spoke with also stated that applicants must meet their program criteria. For one verification program, more than 75 percent of applicants do not meet the minimum criteria to begin the program, and differences in acceptable quality of materials and processes is often the source of those rejections. An official from the other organization stated that most failures to receive verification are due to mismatch between the label and contents. Of prenatal supplement products sold in the United States, 23 have verification from one of these organizations, as of October 2023.

According to our analysis, third-party verification is not a guarantee of conformity to the amounts on the label. Five of the 12 prenatal supplement products the lab tested stated on their labels that they had undergone some form of third-party verification. We found that, on average, these five verified products performed similarly to the non-verified products, although none of the products with third-party verification had nutrient levels present in amounts that may cause a health concern.

Officials from both verification organizations we spoke with stated that they do not have direct coordination roles with FDA or other federal agencies regarding the dietary supplement verification programs. However, officials from one organization stated that FDA staff do participate as government liaisons on committees and panels that develop and revise organizational standards. Officials from both organizations stated a willingness to coordinate more with federal agencies to strengthen public-private partnerships around dietary supplements.

## What concerns do experts have, and what could be done to improve the safety of prenatal supplements?

Experts and stakeholders we spoke to identified a variety of challenges regarding dietary supplements and their oversight.[26] In this section, we discuss some of those challenges and possible opportunities to address them.

### Lack of standardization

Because there is no federal definition or regulation specific to prenatal supplements, manufacturers have no requirements for the types and amounts of nutrients that should be in a prenatal supplement. As a result, prenatal supplements vary in which vitamins and minerals are included. For example, none of the prenatal gummies we tested contained iron, and one softgel did not contain iodine. Moreover, prenatal supplements vary in the labeled amount of each ingredient. For example, label values for vitamin C among the 12 samples we tested ranged from 20 milligrams to 120 milligrams per serving (17 to 100 percent of the daily value for pregnant and lactating individuals).

To explore standardization, NIH's Office of Dietary Supplements will be leading a workshop in June 2024 on prenatal supplements, according to officials. The primary objective is to explore the amounts of various ingredients in prenatal

supplement products and determine whether there is sufficient information available to establish appropriate ranges of vitamins and minerals in those products.

### Lack of research

According to experts and the literature, there are a limited number of high-quality, large, randomized controlled trials to evaluate the benefits or potential harms of routine supplementation of many nutrients during pregnancy. There is evidence for the benefits of supplementation of iron and folic acid during pregnancy. However, according to experts from ACOG, there is limited evidence for the benefit of other nutrients to pregnancy outcomes. According to experts and the literature, additional research could help determine which nutrients are necessary for supporting healthy pregnancy outcomes. This knowledge could also be used to develop a standardized definition for prenatal supplements.

### Risks of label mismatch

As our results show, the amount of certain nutrients present within a prenatal supplement does not always match the label. According to officials from USDA, NIH, and two other stakeholders, it is common for several nutrients within dietary supplements to be present at higher levels than the amounts stated on the label rather than at lower levels.[27] This is because of shelf life stability concerns (i.e., the nutrient levels may decrease as time passes) paired with FDA's requirement that a dietary supplement contain at least 100 percent of the label value for each class I nutrient at the expiration date of the supplement, if given.[28] According to USDA officials, most minerals, like iron, are usually closer to the label value than vitamins. USDA officials partly attribute the high amount of variability for vitamins to their low stability in supplement form.

For safety, the NIH website advises that consumers follow the instructions on the label when taking dietary supplements. According to an NIH fact sheet, vitamin D toxicity has been caused both by consumption of supplements with excessive amounts of the nutrient present through manufacturing errors, as well as from excessive intake of supplements.

Moreover, supplements may also contain potentially harmful substances, such as heavy metals, that are not present on the label. FDA conducted two studies investigating heavy metal contamination of prenatal supplements: one 2008 study investigated lead in over-the-counter dietary supplements for women and children—including prenatal supplements—and a 2020 study investigated lead, cadmium, arsenic, and mercury in prescription prenatal supplements.[29] FDA concluded in both studies that, although most of the tested supplements contained heavy metals, none were at levels of health concern. In 2018, a peer-reviewed study investigated prenatal supplements and showed similar results.[30]

Additional testing, such as third-party verification, could help ensure that prenatal supplements contain nutrients consistent with the amounts claimed on their labels and that supplements with possible health risks do not enter the market.

### Limited market knowledge

There is no list of all dietary supplements currently on the U.S. market, according to FDA officials. This is because there is no requirement, in most cases, for firms to notify FDA that a dietary supplement is coming to the market. Furthermore, as discussed earlier, because dietary supplements are considered a category of food, FDA does not generally conduct any pre-market quality or safety testing. For prenatal supplements, this could lead to unfavorable health and pregnancy outcomes for vulnerable populations. FDA officials stated that they have concerns over these limitations and the agency's inability to maintain a complete list of dietary supplements available to consumers to inform its oversight and enforcement of dietary supplements. NIH's Dietary Supplement Label Database contains label information for dietary supplements submitted voluntarily by manufacturers and marketers. According to FDA officials, this database helps to address some of those issues, but it is still a voluntary database and therefore incomplete.[31]

Prior GAO work also found that FDA faces challenges related to limited information about the dietary supplement market.[32] Because of our recommendation in GAO-09-250, FDA unsuccessfully sought additional authority to require registration of dietary supplements. FDA and a dietary supplement trade association have publicly backed proposed legislation to increase FDA's oversight of dietary supplements, such as through the requirement of firms to register each product on the market with FDA. All three stakeholders we interviewed also supported additional oversight of dietary supplements by FDA.

## Conclusions

The limited reach of FDA's oversight over dietary supplements—including prenatal supplements—could lead to unfavorable health outcomes for vulnerable populations (i.e., pregnant individuals and fetuses). FDA does not have a systematic mechanism to identify when dietary supplements that do not contain new dietary ingredients enter the market. When FDA does not know a product is on the market, it cannot conduct testing or inspections and may not be aware of the totality of the market. Moreover, reliance on post-market monitoring may cause FDA to miss cases of misbranding. In fact, our testing results show that there was at least one nutrient above or below the USP thresholds in 11 of 12 prenatal supplement products. Additional authority for FDA to oversee dietary supplements could address some of the concerns identified in our review.

## Matter for Congressional Consideration

Congress should consider measures for allowing FDA sufficient authority to carry out its oversight of dietary supplements. Such measures could include allowing FDA to require dietary supplement manufacturers to notify or register with FDA prior to putting a supplement on the market and to provide a copy of the supplement label. (Matter for Consideration 1)

## Agency Comments

We provided a draft of this report to the Department of Health and Human Services (FDA and NIH) for review and comment. We also discussed the Matter with FDA and it agreed with the wording and intent of the Matter after its review of the report. FDA and NIH also provided technical comments, which we incorporated as appropriate.

## How GAO Did This Study

To describe FDA's role in the oversight of prenatal supplements, we reviewed federal regulations, FDA guidance, prior GAO reports, and peer-reviewed publications. We interviewed FDA officials and obtained data on fiscal year 2022 enforcement actions for dietary supplements. We determined that the sources of the data and the methods used were sufficiently reliable for reporting on FDA's enforcement actions taken in the dietary supplement space, with certain limitations as noted in the report. We also interviewed officials from NIH and USDA to provide more context on the work they have conducted on dietary supplement label verification and contamination studies.

To determine the extent to which selected over-the-counter prenatal supplements contain the amounts of key vitamins and minerals stated on the label or potentially harmful contaminants, we contracted with an accredited analytical laboratory to conduct blind testing of three different lots of each of 12 selected prenatal supplement products. We selected six nutrients and four heavy metal contaminants for testing based on a review of the literature and information available online from expert organizations. Based on this review, we selected: three of the most frequently recommended nutrients to supplement (iron, iodine, and vitamin B9/folic acid); three vitamins that are beneficial in low doses but could be toxic to the fetus in large doses or in certain combinations (vitamins A, C, and E); and four heavy metals that FDA prioritizes for reducing exposure (lead, cadmium, arsenic, and mercury).

We tested a nongeneralizable sample of prenatal supplement products selected from a list of "best-selling" or "top-rated" prenatal supplements from the websites of major retailers and compared these to "best of" lists found online. We selected 12 products—five gummies, four softgels, and three tablets—based on their ranking on these lists, the availability of the products from major retailers, and whether they contained the majority of our selected ingredients while also ensuring brand variability. Eleven different brands are represented across the 12 products, with one brand present in both softgel and gummy forms. We purchased three different lots of each supplement product online and in stores for a total of 36 samples. All supplement products were blinded—transferred to nondescript secondary containers—under supervision from an independent witness unaffiliated with our core team, then sent to the laboratory for analysis. All samples—except for the gummy forms—underwent quantitative testing for all the selected ingredients and potential contaminants. The gummy form samples were not tested for iron due to its absence from their labels.

The results of this testing are limited to the prenatal supplement samples we tested and are not generalizable to the entire universe of prenatal supplements. The results are also limited to the selected ingredients and contaminants, and therefore it is unknown whether other contaminants are present in the selected supplements. However, we determined that these tests were suitable for our intended purposes. We did not test the efficacy of the selected prenatal supplements. At FDA's request, we provided FDA with all of our prenatal supplement testing data for review and possible action, if appropriate.

Technical experts from GAO—including an analytical chemist—interviewed scientists from the testing laboratory and reviewed all data and results related to the testing of the prenatal supplement samples discussed in this report.

Specifically, we reviewed the laboratory's instrumental methods; testing protocols; and quantitative results, including validation data. We determined that the laboratory data were sufficiently reliable for our purposes.

To gain contextual information for the testing results, we interviewed nongeneralizable samples of different stakeholders and experts including: two organizations that conduct independent testing of dietary supplements (USP and NSF—an independent organization formerly known as the National Sanitation Foundation), a trade association representing dietary supplement manufacturers (the Council for Responsible Nutrition), and a group of medical professionals who provide care for patients who take prenatal supplements (obstetricians and gynecologists affiliated with ACOG).

We conducted this performance audit from March 2023 to December 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## List of Addressees

The Honorable Jon Ossoff
Chair
Subcommittee on Human Rights and Law
Committee on the Judiciary
United States Senate

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Senate Subcommittee on Human Rights and the Law of the Committee on the Judiciary and the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at https://www.gao.gov.

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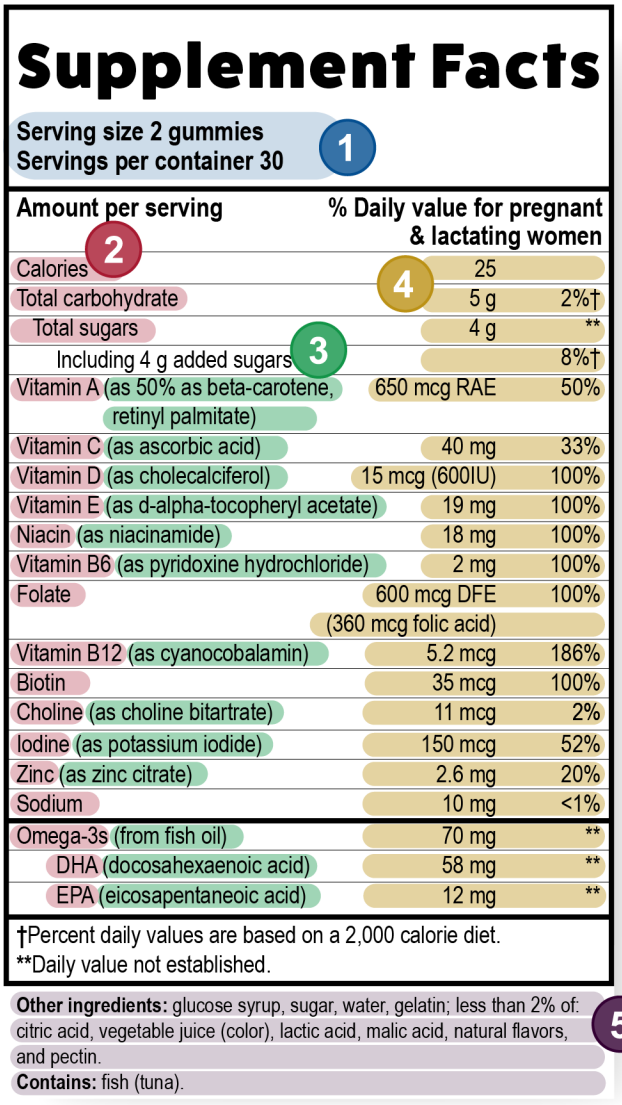
## Appendix I. How to Read a Prenatal Supplement Facts Label

**Figure 5. Important components of a prenatal supplement facts label with a brief description of each**



**Supplement Facts**

**Serving size 2 gummies** (1)
**Servings per container 30**

| Amount per serving (2) | | % Daily value for pregnant & lactating women (4) |
|---|---|---|
| Calories | 25 | |
| Total carbohydrate | 5 g | 2%† |
| Total sugars | 4 g | ** |
| Including 4 g added sugars (3) | | 8%† |
| Vitamin A (as 50% as beta-carotene, retinyl palmitate) | 650 mcg RAE | 50% |
| Vitamin C (as ascorbic acid) | 40 mg | 33% |
| Vitamin D (as cholecalciferol) | 15 mcg (600IU) | 100% |
| Vitamin E (as d-alpha-tocopheryl acetate) | 19 mg | 100% |
| Niacin (as niacinamide) | 18 mg | 100% |
| Vitamin B6 (as pyridoxine hydrochloride) | 2 mg | 100% |
| Folate | 600 mcg DFE (360 mcg folic acid) | 100% |
| Vitamin B12 (as cyanocobalamin) | 5.2 mcg | 186% |
| Biotin | 35 mcg | 100% |
| Choline (as choline bitartrate) | 11 mcg | 2% |
| Iodine (as potassium iodide) | 150 mcg | 52% |
| Zinc (as zinc citrate) | 2.6 mg | 20% |
| Sodium | 10 mg | <1% |
| Omega-3s (from fish oil) | 70 mg | ** |
| DHA (docosahexaenoic acid) | 58 mg | ** |
| EPA (eicosapentaneoic acid) | 12 mg | ** |

†Percent daily values are based on a 2,000 calorie diet.
**Daily value not established.

**Other ingredients:** glucose syrup, sugar, water, gelatin; less than 2% of: citric acid, vegetable juice (color), lactic acid, malic acid, natural flavors, and pectin. (5)
**Contains:** fish (tuna).

1. The serving size for dietary supplements is the number of pills, tablets, or gummies that need to be taken to consume the amounts of the nutrients listed on the supplement facts label. If you do not consume the full serving size or consume more than the serving size, you will not consume the nutrient dosage intended by the manufacturer of the supplement. Consuming too much of a supplement could result in vitamin toxicity with fat-soluble vitamins such as vitamins A, D, and E.

2. The supplement facts label will include some of the nutrients in the product. There are no required ingredients or ingredient levels for prenatal supplements, so it is important to ensure that a prenatal supplement includes the nutrients and nutrient levels recommended by your health care provider.

3. The specific chemical form of each ingredient on the supplement facts label will be listed either in the label or in the "other ingredients" section of the label. Some nutrients, like vitamin A, can have different chemical forms which can be absorbed by your body to different degrees.

4. Percent daily values provide the percent of the daily value included in one serving of the product for each nutrient. Daily values for pregnant and lactating individuals, established by the Food and Drug Administration (FDA), are the reference daily intake values for that group—the amount of a nutrient that is equal to or greater than what the average American needs per day. These values are based on Dietary Reference Intakes published by the Institute of Medicine.

5. Ingredients not listed on the supplement facts label but included in the product will be provided here. If the chemical form of a nutrient is not listed next to the nutrient on the supplement facts label, it can be found in this section.

Source: GAO summary of prenatal supplement fact labels, federal code, and information from FDA, National Institutes of Health, and American College of Obstetricians and Gynecologists. | GAO-24-106689

## Endnotes

[1]According to one independent market research group.

[2]For the purpose of this report, we define prenatal supplements as any supplement that self-identified on the label as being a prenatal supplement.

[3]Food and Drug Administration, "Questions and Answers on Dietary Supplements," Accessed: March 17, 2023. https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements

[4]FDA considers class I nutrients below 100 percent of label amounts to be misbranded, according to FDA officials. In our analysis, we assume all tested nutrients in all tested supplements to be class I nutrients (added nutrients in fortified or fabricated foods) and not class II nutrients (naturally occurring nutrients). FDA does not have an upper limit for the amount of nutrients permitted in a dietary supplement, and officials stated that FDA examines each product on a case-by-case basis to determine whether the level of nutrient in the product is a safety risk.

[5]The thresholds given by USP are percentages of allowable deviation from the stated amounts on the label, and do not have actual amounts of a particular nutrient tied to them. This is why USP thresholds are not metrics of safety. Tolerable upper intake levels are based on the actual amount of a nutrient that an individual may consume. These levels define an amount that is the maximum allotted exposure before harm may occur and are therefore metrics of safety. Institute of Medicine (US) Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, "Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Vitamins," *Dietary Reference Intakes for Calcium and Vitamin D,* (Washington, D.C.: 2011). National Academies of Sciences, Engineering, and Medicine, "Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Elements" *Dietary Reference Intakes for Sodium and Potassium,* (Washington, D.C.: 2019).

[6]National Institutes of Health, Office of Dietary Supplements*, Folate: Fact Sheet for Health Professionals* (November 2022), Accessed July 18, 2023. https://ods.od.nih.gov/factsheets/Folate-HealthProfessional

[7]While the testing laboratory did confirm that all samples were fully dissolved during extraction procedures, they were not able to provide a metric for extraction efficiency for their methodology. Therefore, while we did determine that their data were sufficiently reliable to report, it is possible that these low values are due to incomplete extraction or sample deterioration.

[8]Food and Drug Administration "Environmental Contaminants in Food", Accessed October 4, 2023. https://www.fda.gov/food/chemical-contaminants-pesticides/environmental-contaminants-food

[9]Fong Sam, J.; Andrews, K; Kuszak, A. "Toxic Elements in Prescription Prenatal Supplements" Presented at the Winter Conference on Plasma Spectrochemistry, Tucson, AZ, January 13-18, 2020.

[10]21 C.F.R. 111.70(b)(3) and 21 C.F.R. 111.70(e)

[11]The Federal Trade Commission (FTC) shares responsibility with FDA for overseeing dietary supplements. FTC is responsible for preventing false advertising for dietary supplements and most other products sold to consumers under the Federal Trade Commission Act. 15 U.S.C. § 45 and 15 U.S.C. § 52. FTC's oversight role is outside of the scope of this report. For more information on FTC's role in oversight of dietary supplements, see GAO, *Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness*, GAO-17-416 (Washington, D.C.: May 16, 2017).

[12]21 U.S.C. §§ 301-399

[13]Under DSHEA, Pub. L. No. 103-417, FDA regulates dietary supplements, including vitamins, minerals, herbals and other botanicals, amino acids, certain other dietary substances, and derivatives of these items.

[14]21 U.S.C. § 321(ff) defines a dietary supplement in part as a product that, among other requirements, is intended to supplement the diet; contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents; is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a dietary supplement.

[15]GAO-17-416.

[16]FDA's principal pre-market regulatory role for dietary supplements is reviewing New Dietary Ingredient notifications. See 21 U.S.C. § 350b. However, according to FDA officials, these are not typically relevant to prenatal supplements.

[17]For the purpose of this report, we use the term "enforcement" to refer to actions an agency takes against a dietary supplement firm or product after a violation has been identified—this includes advisory communications and regulatory actions (administrative and judicial court actions) taken by FDA.

[18]Products may include "proprietary blends," which must list all ingredients but do not need to list the amount of each ingredient.

[19]One way in which a dietary supplement is considered misbranded is if its labeling is false or misleading. See 21 U.S.C. § 343(a). According to USP officials, if a dietary supplement product label says the product is covered by USP standards and fails to conform to those standards, that product may be deemed misbranded.

[20]The Federal Food, Drug, and Cosmetic Act, as amended by the 2006 Dietary Supplement and Non-prescription Drug Consumer Protection Act, requires that firms with their names appearing on the label report information about any serious adverse event report they receive to FDA within 15 business days of receipt. See 21 U.S.C. § 379aa-1.

[21]The FDA Safety Reporting Portal can be found at: https://www.safetyreporting.hhs.gov/.

[22]FDA uses a risk-based approach to inspect facilities that manufacture foods, including dietary supplements. According to FDA officials, and consistent with the FDA Food Safety Modernization Act, Pub. L. No. 111-353,§ 201(a), 124 Stat. 3885, 3922 (2011) (adding 21 U.S.C.§ 350j(a)), the agency inspects facilities it deems as high risk once every 3 years and other facilities once every 5 years.

[23]FDA may initiate a mandatory recall if the responsible party refuses to conduct a voluntary recall after FDA has determined that there is a reasonable probability that the food (including a dietary supplement or dietary ingredient) is contaminated or is misbranded for failure to declare a major allergen on the label, and the use of or the exposure to the dietary supplement will cause serious adverse health consequences or death to humans or animals.

[24]According to FDA officials, there is no product code FDA can search for prenatal supplements. As a result, FDA could only provide GAO summary data for all dietary supplement inspections. Moreover, to provide the number of prenatal supplements analyzed, FDA searched the relevant databases using variations of the word "prenatal" and therefore the accuracy of the resulting data is reliant on how a supplement was classified by the person inputting the information.

[25]FDA reviews all import entry lines containing FDA-regulated products—including dietary supplements, according to FDA's website. In fiscal year 2022, FDA reviewed over 100,000 import entry lines for dietary supplements coming into the U.S. through import processes—including 272 for prenatal supplements. According to FDA, an entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately. To provide the number of prenatal supplement imports examined, FDA searched the relevant databases of entry lines using variations of the word "prenatal" and therefore the accuracy of the resulting data is reliant on how a supplement was classified by the person inputting the information.

[26]Stakeholders refers to representatives from USP, the Council for Responsible Nutrition, and NSF. NSF—formerly known as the National Sanitation Foundation and NSF International—is a standard setting organization and is not the National Science Foundation, which is a federal agency.

[27]NIH officials stated that NIH's observations in regard to nutrient content versus label amounts come from collaborative work between NIH and USDA that is publicly available at https://dsid.od.nih.gov/.

[28]Class I and II nutrients are defined in endnote 4. Class II nutrients, if present, must be at least 80 percent of the label value during the shelf life of the product. 21 C.F.R. 101.9(g)(4).

[29]Mindak, W. R. et al., "Lead in Women's and Children's Vitamins," *Journal of Agricultural and Food Chemistry,* vol. 56 (2008): 6892. https://doi.org/10.1021/jf801236w and Fong Sam, J.; Andrews, K.; Kuszak, A., "Toxic elements in Prescription Prenatal Supplements." Presented at the Winter Conference on Plasma Spectrochemistry, Tucson, AZ, January 13-18, 2020.

[30]Schwalfenberg, G. et al., "Heavy metal contamination of prenatal vitamins," *Toxicology Reports*, vol. 5 (2018): 390. https://doi.org/10.1016/j.toxrep.2018.02.015

[31]The Council for Responsible Nutrition maintains its own supplement label database—the Supplement Online Wellness Library (OWL)—and requires all members to participate, according to Council officials. CRN officials stated that publicly available label data are then shared with NIH's label database. Officials from NIH stated that both CRN and NIH work with the Therapeutic

Research Center, and any sharing of label record information would occur through this center as an intermediary.

[32]GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250, (Washington, D.C.: Jan. 29, 2009), GAO-17-416, and GAO, *Memory Supplements: Results of Testing for Selected Supplements,* GAO-19-23R, (Washington, D.C.: Oct. 18, 2018).