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Summary of FDA-Mandated Labeling Changes

Due to changes in FDA labeling requirements, you will see changes to many of the supplement facts on the labels. In most cases, our actual product formulas have not changed but it might look like they have. Here is a list of the changes that will begin appearing on rebranded human product labels. The regulations for animal health products have not changed.

- **Added sugar:** Non-naturally occurring sugars must be labeled as added sugar. If it has been added into a formulation for sweetening, even from a natural source like evaporated cane juice sugar, it will fall into this category. This is to distinguish between, for example, ingredients like pea protein that might naturally contain sugars that have not been added. The total sugars on a label will be the added sugar plus the sugar that naturally occurs in an ingredient.

- **Vitamin A**: This ingredient will be based on the unit of measure known as RAE or Retinol Activity Equivalence. It will appear on the label only as mcg or mg. We are not allowed to list the IUs, even in parentheses. Customers will want to know how many IUs are in the product because that is what they are used to. Conversion from mcg to IU is mcg amount/0.3 = IUs. For example, if there a 750 mcg of vitamin A listed on the label, you divide that by 0.3 and get 2,500 IUs.

- **Beta-carotene**: This ingredient will be based on the unit of measure known as RAE or Retinol Activity Equivalence. This ingredient will also appear on the label only as mcg or mg. We are not allowed to list the IUs, even in parentheses. Conversion from IU to RAE for beta-carotene is mcg amount/0.15 = IUs. If a product has 1,875 mcg, you divide by 0.15 and get 12,500 IUs.

- **Vitamin D3**: This ingredient will be moving from IU to mcg on the label for the primary claim. The IU amount will be listed in parentheses. In case there are questions 1 mcg = 40 IUs. So our D-1,000 which has 1,000 IUs of D3 will equate to 25 mcg.

- **Vitamin E**: Alpha-tocopherol has been listed as IUs. It is changing to mgs. To convert mgs to IUs, multiple the reported mg amount by 1.49. For example, 268 mg x 1.49 = 400 IUs. For questions on mixed tocopherols, please contact medical affairs.

- **Folate**: This ingredient has a new unit of measure called Dietary Folate Equivalents (DFE). Our sources of folate are considered more potent than food forms of folate, and as such will have a higher DFE than a food source. We have not changed the original formulations, but you will see an increased label claim and %DV. Conversion is the old folate claim x 1.7. So, for example 1 mg of 5MTHF (as it was listed on a previous label) will be listed as 1.7 mg DFE, no matter what the folate source (L-MTHF and/or Folinate). The actual amount of folate we are putting in the supplements is the same as always and will be noted in parentheses.

- **Choline**: Choline now has an %DV. Therefore, the amount of choline (not the amount of the entire choline citrate molecule) needs to be listed. Thus, it will look like we have less choline in our products, whereas they have the same amount they always had. Choline citrate is 35% choline; so, whereas the old labels might have said 100 mg of choline citrate, the new label will say 35 mg of choline (as choline citrate).

- **Iron, Calcium, Potassium and Vitamin D**: These four vitamins and minerals have been deemed by FDA as nutrients of public health significance and are considered mandatory for labeling purposes. Previously Vitamins A and C were considered mandatory until they were replaced by Vitamin D and Potassium. These four nutrients have been added to what is known as the B2 column ingredients. If one serving of one of these ingredients in a product has 2% or more of the RDI (listed on the label as % DV), it must be listed on the label. The declaration of all other vitamins and minerals on a label are voluntary unless such nutrient is added for therapeutic purposes or if a claim is made about the nutrient.

- Consider ingredients that are found naturally in something like a protein powder but that we don't add specifically for therapeutic purposes. You might see claims on our protein powders, of iron for example, without a source (it will be simply listed as iron, not iron (bisglycinate)). This indicates it is naturally occurring in one or more of the ingredients. No formulation changes have taken place.

- Another example of the above rule is a product that has an ingredient that is not added for its therapeutic value – calcium in calcium undecylenate or calcium glucarate, for example. The calcium is not in there as a calcium source to help build bones but is to make the material it is bound to more stable. However, if the amount of calcium in a serving is 2%DV or more, it has to be listed on its own line with the amount.

- Some things that used to appear on labels are not required anymore so we have removed them. An example is chloride in the products Glucosamine Sulfate and AR-Encap (part of the glucosamine sulfate – potassium chloride complex). Chloride is still in the product but it's not listed as a separate ingredient on the label.

- The FDA has established new %DVs for some nutrients. What this means is that a government agency has decided to increase or decrease the daily recommendation of a particular nutrient to maintain health. Therefore, even if the amount of the nutrient in the formula didn't change, the %DV might change. Nearly all nutrients with RDIs have changed – some more than others. Below is a chart of the new RDIs for various populations.

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Comparison chart of old versus new RDIs for adults and children 4+ years:

Nutrient	Previous RDI	New RDI
Vitamin A	5,000 IU	900 mcg (3,000 IU)
Vitamin C	60 mg	90 mg
Vitamin D	400 IU	20 mcg (800 IU)
Vitamin E	30 IU	15 mg
Vitamin K	80 mcg	120 mcg
Thiamin	1.5 mg	1.2 mg
Riboflavin	1.7 mg	1.3 mg
Niacin	20 mg	16 mg
Vitamin B6	2 mg	1.7 mg
Folate	400 mcg	400 mcg
Vitamin B12	6 mcg	2.4 mcg
Biotin	300 mcg	30 mcg
Pantothenic Acid	10 mg	5 mg
Calcium	1,000 mg	1,300 mg
Iron	18 mg	18 mg
Phosphorus	1,000 mg	1,250 mg
Iodine	150 mcg	150 mcg
Magnesium	400 mg	420 mg
Zinc	15 mg	11 mg
Selenium	70 mcg	55 mcg
Copper	2 mg	0.9 mg
Manganese	2 mg	2.3 mg
Chromium	120 mcg	35 mcg
Molybdenum	75 mcg	45 mcg
Chloride	3,400 mg	2,300 mg
Sodium	2,400 mg	2,300 mg
Potassium	3,500 mg	4,700 mg
Choline	No RDI	550 mg

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New RDIs for all populations

RDIs - Nutrients					
Nutrient	**Unit of measure**	**Adults and Children ≥ 4 years**	**[1]Infants through 12 months**	**Children 1 through 3 years**	**Pregnant women and lactating women**
Vitamin A	Micrograms RAE[2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg)[3]	20	10	15	15
Vitamin E	Milligrams (mg)[4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE[5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2
Folate[6]	Micrograms DFE[7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Choline	Milligrams (mg)	550	150	200	550