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# INTERNAL CLIENT MEMO

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TO: Ron Elul, CuraLife

DATE: September 6, 2017

RE: CuraLin Ingredient Review

## SUMMARY

The ingredients listed in Table A below as used in the dietary supplement labeled CuraLin are permitted for use in dietary supplements and do not require submission of one or more New Dietary Ingredient Notifications to the U.S. Food & Drug Administration ("FDA").

## REGULATORY OVERVIEW

The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. (See section 413(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 350b(d)). There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994.

The term "dietary ingredient" means a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients (*See* section 201(ff)(1) of the FD&C Act (21 U.S.C 321(ff)(1)).

The FD&C Act provides that a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)) unless it meets one of two requirements. First, 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. Second, an NDI submission is made based on 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.

## STATUS OF INGREDIENTS

All of the ingredients used in the dietary supplement labeled CuraLin are herbs or other botanicals that qualify as dietary ingredients under section 201(ff).

It is possible the ingredients have been used in dietary supplements in the United States prior to October 15, 1994 but more likely have been present in the food supply as articles used for food in a form in which the food has not been chemically altered (21 U.S.C. § 350b(a); 21 U.S.C. § 350b(d)).

Therefore, as of the date of this review, the formulation of CuraLin is in compliance with federal laws and regulations currently enforced by the U.S. Food and Drug Administration ("FDA") and the product is eligible for importation and sale in the United States.

Table A	
Ingredient	Status
Karela (Mormordica charantia, Bitter Melon, Balsam Pear)	<b>Botanical</b>
Eugenia Jambolana Jambubeej/ Syzygium Cumini, Java plum, Malabar plum	<b>Botanical</b>
Kariyatu (Swertia Chirata or andrographis paniculata)	<b>Botanical</b>
Methi (Trigonella foenum Graecum, Fenugreek)	<b>Botanical</b>
Neempan, Neem, Indian Lilac (Melia Azadirachta or Azadirachta indica)	<b>Botanical</b>
Gudmaar (Gymnema Sylvestre, Cowplant)	<b>Botanical</b>
Amla (Embllica Officinalis), Phyllanthus Emblica, Myrobalan, Indian gooseberry, Malacca tree	<b>Botanical</b>
Galo (Tinospora sagittata)	<b>Botanical</b>
Kadu, Kutki (Picrorhiza Kurroa)	<b>Botanical</b>
Haldi (Curcuma longa, Tumeric, Curcurma domestica Valeton )	<b>Botanical</b>

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Marc C. Sanchez, Esq.

