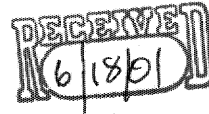


June 15, 2001



Office of Special Nutritionals (HFS-450)  
Center for Food Safety & Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, DC 20204

Dear Sir/Madam:

Pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act and 21 CFR § 101.93, CollaGenex is providing herewith, Notification that it is marketing the dietary supplement, Dentaplex™.

If you have questions concerning this Notification, please contact the undersigned at 215-579-7388 (telephone) or 215-579-8577 (fax).

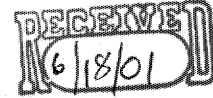
Sincerely,

A handwritten signature in black ink, appearing to read "Christopher Powala".

Christopher Powala  
Sr. Director, Drug Development  
& Regulatory Affairs

97S 0162 LET 8223

**NOTIFICATION PURSUANT TO  
SECTION 403(r)(6) OF FDCA  
AND 21 CFR § 101.93**



Pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act and 21 CFR § 101.93, CollaGenex Pharmaceuticals, Inc. is hereby filing a notification of its intent to distribute the dietary supplement, Dentaplex™. CollaGenex's business address is: 41 University Drive, Newtown, PA 18940.

The following table identifies each dietary ingredient or supplement and provides the corresponding structure-function statements:

<b>Vitamins</b>	<b>Structure-Function Statement</b>
Vitamin A	<ul style="list-style-type: none"> <li>• Essential for the normal growth and maintenance of oral epithelial tissues and bones that surround and support teeth</li> <li>• As an antioxidant, protects cells by neutralizing free radicals that cause oxidative cellular damage</li> </ul>
B Complex - riboflavin - thiamine - folic acid - pyridoxine - cyanocobalamin	<ul style="list-style-type: none"> <li>• Important for normal growth and repair of tissue in the mouth</li> <li>• Helps maintain the body's normal immune function.</li> </ul>
Vitamin C	<ul style="list-style-type: none"> <li>• Important for normal growth and repair of tissue in the mouth</li> <li>• As an antioxidant, protects cells by neutralizing free radicals that cause oxidative cellular damage</li> </ul>
Vitamin D	<ul style="list-style-type: none"> <li>• Essential for normal development and maintenance of teeth and bones that surround and support teeth</li> <li>• Helps regulate absorption and use of calcium and phosphate, which are necessary to maintain healthy bone</li> </ul>
Vitamin E	<ul style="list-style-type: none"> <li>• As an antioxidant, protects cells by neutralizing free radicals that cause oxidative cellular damage</li> </ul>

Minerals	Structure-Function Statement
Calcium	<ul style="list-style-type: none"> <li>• Essential to the normal development and maintenance of teeth and the bone that surrounds and supports teeth</li> </ul>
Magnesium	<ul style="list-style-type: none"> <li>• Helps maintain normal bone formation and regeneration</li> </ul>
Copper	<ul style="list-style-type: none"> <li>• Important in stabilizing newly formed tissues in the mouth</li> </ul>
Molybdenum	<ul style="list-style-type: none"> <li>• Plays a role in the normal growth and maintenance of the bone that surrounds and supports teeth, dentin, and enamel</li> </ul>
Selenium	<ul style="list-style-type: none"> <li>• As an antioxidant, protects cells by neutralizing free radicals that cause oxidative cellular damage</li> </ul>
Vanadium	<ul style="list-style-type: none"> <li>• Required for the formation and maintenance of healthy bones and teeth</li> </ul>
Zinc	<ul style="list-style-type: none"> <li>• Essential to the normal immune function, and general growth of all tissues</li> <li>• Helps maintain normal sense of taste</li> </ul>

I, Christopher Powala, Sr. Director of Drug Development and Regulatory Affairs at CollaGenex Pharmaceuticals, Inc. am authorized to certify this Notification on behalf of the company. I certify that the information contained in this Notification is complete and accurate and that CollaGenex has substantiation that each structure-function statement is truthful and not misleading.

Dated this 15th Day of June, 2001.

By:



\_\_\_\_\_  
Christopher Powala  
Sr. Director, Drug Development  
& Regulatory Affairs