



Memorandum

Date . November 3, 2003

From Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject CAP No. 5C0247 – Bone black (twice-burned washed
bone char) for use in cosmetics including use in the
area of the eye.

To Division of Petition Review (HFS-265)
Attention: Judith Kidwell
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG *LIB*



Ebonex Corporation
PO Box 3247
Melvindale, MI 48122

Attached is the Finding of No Significant Impact (FONSI) for CAP 5C0247. This FONSI supersedes the FONSI dated September 19, 1996. When the petition is ready to be regulated, please forward a copy of the following information to the Division of Dockets Management:

1. This FONSI
2. The petitioner's revised Environmental Assessment, dated September 15, 2003.

Please let us know if there is any change in the identity or use of the color additive or if any comments were submitted for this petition.

Annette M. McCarthy, Ph.D.



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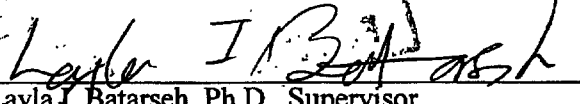
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**FINDING OF NO SIGNIFICANT IMPACT
FOR**

Color Additive Petition 5C0247, submitted by Ebonex Corporation, to amend 21 CFR 74 to provide for the safe use of bone black (twice-burned washed bone char) as a color additive in cosmetics including use in the area of the eye.

The Environmental Review Group has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment dated September 15, 2003.

Prepared by  Date: November 3, 2003
Annette McCarthy, Ph.D., Environmental Toxicologist
Environmental Review Group
Division of Chemistry Research and Environmental Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by  Date: November 3, 2003
Layla Batarseh, Ph.D., Supervisor
Environmental Review Group
Division of Chemistry Research and Environmental Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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