

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 1-504

Trade Name: Verard

Sponsor: The Verard Company

Approval Date: August 30, 1939

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 1504

The Verard Company,
119 West 227th Street,
New York, New York.

AUG 30 1939

Gentlemen: Attention of Mr. Frederic Arden

VI We have your application dated August 18, addressed to the Secretary of Agriculture under section 505 of the Food, Drug, and Cosmetic Act, with respect to the new drug "Verard Solution". This application was filed with the Secretary on August 19.

Consideration of the application has been completed. It has been concluded that no order will issue under section 505(d) of the Act to refuse to permit the application to become effective.

Your attention is directed to section 505(e) of the Act, which provides for the suspension of the effectiveness of an application if further experience and tests with the article show it to be unsafe for use or if it is found that the application contains any untrue statement of a material fact.

Your attention is directed also to section 301(1) prohibiting the use on the labeling or in any advertising of any statement to the effect that an application with respect to this drug is effective under section 505 or that the drug complies with the provisions of that section.

An application under section 505 which has become effective in no way relieves a drug from compliance with the other provisions of the Food, Drug, and Cosmetic Act. We direct your attention to Public No. 151 which specifically provides that section 302 is now in effect with respect to new drugs. Therefore, the Food, Drug, and Cosmetic Act is in effect in its entirety with respect to this preparation.

Very truly yours,

cc FD NY with labeling
cc Solicitor with labeling
cc Drug Division

J. J. Barrett, M.D.,
Acting Chief.

FWI/hmg
8-29-39

ZWS

511-1504