

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 02-918

Trade Name: Bensulfoid

Generic Name: sulfur bentonite

Sponsor: William P. Poythress & Company, Inc.

Approval Date: September 17, 1940

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APPROVAL LETTER

NDA 2918

SEP 17 1940

Wm. P. Poythress & Company, Inc.
16 N. 22nd Street
Richmond, Virginia

Gentlemen: Attention of Mr. F. C. Campbell

We have your application dated September 10, addressed to the Administrator under section 505 of the Food, Drug, and Cosmetic Act with respect to the new drug "Benzulfoid," which you previously proposed to call (b) (4). The application with respect to Benzulfoid was filed with the Administrator on September 11.

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.

The effectiveness of this application under section 505 in no way relieves you of the necessity of complying with the requirements of all other provisions of the Act applicable to the preparation.

cc ED Balt with cy labeling
cc Gen Counsel with cy "

M
cc Drug Div
FWI/eck
9-16-40 *JWS*

Very truly yours,

J. J. Durrett
Acting Commissioner of
Food and Drugs

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ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

NDA 2918

AUG 26 1940

Wm. P. Hargbress & Company, Inc.
16 N. 22nd Street
Richmond, Virginia

Gentlemen: Attention of Mr. Y. C. Campbell

We have your application dated August 13, addressed to the Administrator under section 505 of the Food, Drug, and Cosmetic Act, with respect to the new drug (b)(4)

In order to complete this application with respect to section 505(b)(4) of the Act it will be necessary to provide (b)(4)

(b)(4) Until this information has been provided the application may not be filed with the Administrator for consideration.

If sulfur is the only active ingredient of this preparation, it should be designated as such on the label. (b)(4)

(b)(4) section 502(f)(1) of the Act. (b)(4)

(b)(4)(b)(2) of the regulation under section 502(f), (b)(4)

The name (b)(4) and you should carefully consider the possibility that this name may be unwarranted under section 502(a) of the Act and the regulations thereunder.

At the time you complete this application with respect to section 505(b)(4) of the Act, you should also submit five copies of appropriately revised labeling for the preparation.

Very truly yours,

J. J. Durrett
Acting Commissioner of
Food and Drugs

cc Mr. Ball
cc Drug Div
FW/eca
8-24-40

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