

Appendix A to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

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/s/

Tamika White
10/30/2008 10:39:45 AM



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODEIII

FACSIMILE TRANSMITTAL SHEET

DATE: October 16, 2008

To: Barry M. Calvarese, MS, Vice President, Regulatory and Clinical Affairs	From: Tamika White, Regulatory Project Manager
Company: Dow Pharmaceutical Sciences, Inc.	Division of Dermatology and Dental Products
Fax number: 707-793-0145	Fax number: 301-796-9895
Phone number: 707-793-2600 x601	Phone number: 301-796-2110
Subject: NDA 50-819	

Total no. of pages including cover: 4

Comments:

Please review and respond to the following information request.

Document to be mailed: YES NO

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NDA 50-819

Please refer to your December 21, 2007, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Acanya™ (clindamycin phosphate and benzoyl peroxide) Gel 1.2% and 2.5%.

We have the following information request:

Based upon our assessment of the labels and labeling, we have identified the following area of needed improvement on the trade container label:

On the trade container label, delete or minimize the graphic of the face to increase readability of the established name and strength. If you choose to minimize the face graphic, you should ensure the graphic does not obscure the proprietary name, established name, and strength. An example of the latter alternative can be found on the trade container lid label (see Figure 2). Alternatively, you may also consider revising the font color of the text to provide a greater color contrast.

Figure 1: Trade Container Label

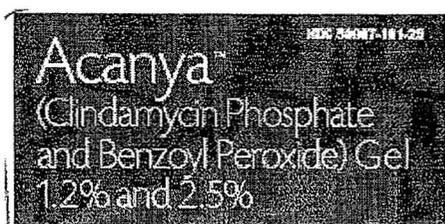


Figure 2: Trade Container Lid Label



Provide the color mock ups with indicated changes as soon as possible but no later than October 20, 2008.

If you have any questions, call Tamika White, Regulatory Project Manager, at 301-796-0310.

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/s/

Tamika White
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CSO



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODEIII

FACSIMILE TRANSMITTAL SHEET

DATE: October 1, 2008

To: Barry M. Calvarese, MS, Vice President, Regulatory and Clinical Affairs	From: Tamika White, Regulatory Project Manager
Company: Dow Pharmaceutical Sciences, Inc.	Division of Dermatology and Dental Products
Fax number: 707-793-0145	Fax number: 301-796-9895
Phone number: 707-793-2600 x601	Phone number: 301-796-2110
Subject: NDA 50-819	

Total no. of pages including cover: 3

Comments:

Please review and respond to the postmarketing request.

Document to be mailed: YES NO

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NDA 50-819

Please refer to your December 21, 2007, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Acanya™ (clindamycin phosphate and benzoyl peroxide) Gel 1.2% and 2.5%.

The Agency has the following postmarketing request:

To conduct a 'maximum use systemic exposure (MUSE)' bioavailability study in the targeted patient population to determine the extent of systemic absorption of the active ingredients in Acanya™ Gel. Elements of the said study should include:

- a) Highest frequency of dosing in the proposed label for Acanya™ Gel
- b) Greatest duration of dosing in the above mentioned labels
- c) Use of to-be-marketed formulation
- d) Maximum total involved surface area to be treated at one time per labeling
- e) Amount applied per square centimeter to be documented
- f) Method of application/site preparation should be documented
- g) Sensitive and validated analytical method to measure active and potential metabolite(s).

Final study protocol submitted:	February 1, 2009
Patient accrual initiated:	May 1, 2009
Study completion:	August 1, 2009
Final report submission:	February 1, 2010

Send a letter stating the commitment as outlined above, and your agreement to the commitment and timetables. We request receipt of your written response no later than 3:00 p.m. on October 6, 2008.

If you have any questions, call Tamika White, Regulatory Project Manager, at 301-796-0310.

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/s/

Tamika White
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