"delayed-onset formulations". Alternatively, the name might be allowed to remain with a qualifying statement in the insert that the formulation has not been shown to produce results superior to the same dose in conventional formulations.

The question of dosage recommendations may arise. We see no objection to giving dosage regimens for each formulation—a t.i.d. regimen and a q.d. regimen, e.g., 25 mg t.i.d. standard formulation or 75 mg. q.d., matrix formulation, in the DOSAGE AND ADMINISTRATION section of the inserts.

Other issues might be raised, but these seem the main ones. Decision options are listed below. We've discussed the name question with Mary McEniry and Ted Byers, who favor deleting the names. They recalled no precedents.

RECOMMENDATION

That option 1 of each Decision group below be approved.

BARRETT SCOVILLE, M.D.

DECISIONS

A. With respect to data on "sustained-action" of anorectics:

(1) Consider the data do not support such claims, e.g., publish follow-up DESI Notices.

Approved_____. Not Approved_____.

(2) Defer decision to establishment of Committee criteria:

Approved_____. Not Approved_____.

B. With respect to drug names:

(1) Delete names which may imply special formulation claims: e.g., "Enduret", "Gradumet", "Dospan", Stedy-Tab", "Spansule" (this also would include disclaimers in insert).

Approved_____. Not Approved_____.

(2) Leave names, but label with a disclaimer.

Approved_____. Not Approved_____.