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Application No.	Ref.	Date
96 305 519.9-2107	JADC/19153	05.01.99
Applicant: Bristol-Myers Squibb Company		

Communication pursuant to Article 96(2) and Rule 51(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(3) and 83(2) and (4) EPC.

Amendments to the description, claims and drawings are to be filed where appropriate within the said period in **three copies** on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

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STOLTNER A H
Primary Examiner
for the Examining Division

EXRE coded

30.12.98 SB

Enclosure(s): 2 page/s reasons (Form 2906)

Registered Letter

Bescheid/Protokoll (Anlage)	Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Date: 05.01.99	Blatt Sheet Feuille: 1	Anmelde-Nr.: Application No.: Demande n°: 96 305 519.9

The examination is being carried out on **the following application documents**:

Description:
Pages 1 to 17 as originally filed

Claims:
Nos. 1 to 12 as originally filed

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1). Claim 1 lacks clarity. The term "..other product which denatures gelatin on degradation" should be properly defined and supported in the description. If there is any support, the applicant is asked to indicate where.

2). The term "about" between ranges renders the scope of claims 3 and 6 unclear and should, therefore, be avoided (cf. the Guidelines, C-III, 4.5a).

3). The term "aspirin" is a registered trade mark and should be acknowledged as such (cf. the Guidelines, C-II, 4.17).

4). Page 8 of the application is not complete as some of the lines do not appear to have been printed.

5). In view of the above, the present application concerns a pharmaceutical dosage unit containing
a). a solid core containing an acid producing pharmaceutical or a "product denaturing gelatin on degradation" and
b). a first coating on said solid core, consisting of a film forming polymer and pepsin, and
c). a gelatin enrobing said first coating.

6). The following documents have been searched and consulted with respect

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to the subject-matter of the present application:

D1: US-A-4 517 173, discloses a pharmaceutical film prepara- tion whereby the film consists of two layers, the first one being a pharmaceutically active ingredient and a water-soluble high polymer material and the other layer consisting of a poor water-soluble polymer. This film preparation does not fall within the scope of the pres- ently claimed dosage unit.

D2: US-A-4 716 042, discloses coated aspirin tablets in order to protect acetylsalicylic acid from decomposition. This is accomplished by incorporation of citric, alginic or glutamic acid prior to the coating procedure of said tablets. There is, however, no disclosure of a dosage unit as depicted in the present application.

D3: US-A-4 775 536, discloses an enteric coated tablet in which a core including a pharmaceutically active ingredient is coated with a film forming polymer and option- ally with an overcoat. This tablet form however does not anticipate the presently claimed unit dosage form.

D4: US-A-4 900 559, discloses a stabilized coated aspirin granule preparation comprising the mixture of aspirin with glutamic acid prior to filling said granules into gelatin capsules. The teaching of D4 as such does not fall either into the ambit of the present application.

7). In view of the cited documents, the subject-matter of the present application is not disclosed nor suggested in the known prior art. The problem of stabilizing aspirin is undoubtedly known in the prior art documents. There is, however, no hint in the above cited documents of how to arrive at the present dosage unit form depicted in items a)-c) of the present claims 1-12, which dosage form also serves to stabilize other therapeutically active ingredients which are subject to hydrolysis on storage. The subject-matter of the present set of claims therefore complies with Arts. 52(1), 54(1) and 56 of the EPC.

A. Stalner