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RESEARCH**

*APPLICATION NUMBER:*  
**21-693**

**PHARMACOLOGY REVIEW**

**PHARMACOLOGY/TOXICOLOGY NDA FILEABILITY CHECKLIST**

NDA Number: 21-693

Applicant: Biovail

Stamp Date: April 01, 2004

Drug Name: Ralivia Flash Dose

Tramadol hydrochloride orally  
disintegrating tablets

IS THE PHARM/TOX SECTION OF THE APPLICATION FILABLE? (Yes or No)

Yes

The following parameters are necessary in order to initiate a full review, i.e., complete enough to review but may have deficiencies.

	Parameters	Yes	No	Comment
1	On its face, is the Pharmacology/Toxicology section organized adequately?	X		No new data were provided under 505(b)(2).
2	Is the section indexed and paginated adequately?	X		Electronic document was filed.
3	On its face, is the section legible?	X		
4	Are ALL the required and requested IND studies completed and submitted in this NDA?		X	No new non-clinical study was requested.
5	If the formulation to be marketed is different from that used in the toxicology studies, has the sponsor made an appropriate effort to either repeat the studies with the to be marketed product or to explain why such repetition should not be required?		X	The sponsor referenced previous findings of safety and effectiveness of tramadol without obtaining right to reference the NDA 20-281. This is a 505(b)(2) application.
6	Are the proposed labeling sections relative to animal Pharmacology/Toxicology appropriate (including human dose multiples based on comparative serum/plasma levels or expressed in mg/m <sup>2</sup> ) and in accordance with CFR 21, part 201.57?	X		
7	Has the sponsor submitted all special studies/data requested by the Division during pre-NDA meeting?		X	See comment # 4.

Reviewing Pharmacologist:

\_\_\_\_\_  
Asoke Mukherjee

Team Leader:

\_\_\_\_\_  
Josie W.C. Yang

Date: \_\_\_\_\_

cc:

Original NDA 21-693  
HFD-550/Division File  
HFD-550/Pharm-Tox/A. Mukherjee  
HFD-550/Pharm-Tox TL/JYang  
HFD-550/CSO/ Kathleen Reedy

NDA21-693 checklistMay03, 2004.doc  
May 3, 2004

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/s/  
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Asoke Mukherjee  
5/4/04 09:34:39 AM  
PHARMACOLOGIST

Josie Yang  
5/4/04 10:29:33 AM  
PHARMACOLOGIST