

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022432Orig1s000

PHARMACOLOGY REVIEW(S)

**45 Day Meeting Checklist
NONCLINICAL PHARMACOLOGY/TOXICOLOGY**

NDA No. 8-372/HP Acthar gel (Corticotropin) for infantile spasms/April 23, '07

ITEM	YES	NO	COMMENT
1) Does this section of the NDA appear to be organized (according to 21 CFR 314 and current guidelines for format and content) in a manner that would allow a substantive review to be completed?			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
2) Is this section of the NDA indexed and paginated in a manner to enable a timely and substantive review?			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
3) Is this section of the NDA sufficiently legible so that a substantive review can be done? Has the data been presented in an appropriate manner (consider tables, graphs, complete study reports, inclusion of individual animal data, appropriate data analysis, etc.)?			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
4) Are all necessary and appropriate studies for this agent, including special studies/data requested by the Division during pre-submission communications/discussions, completed and submitted in this NDA? Please itemize the critical studies included and indicate any significant studies that were omitted from the NDA (None)			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.

ITEM	YES	NO	COMMENT
5) Were the studies adequately designed (ie., appropriate number of animals, adequate monitoring consistent with the proposed clinical use, state-of-the art protocols, etc.)?			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
6) If the formulation to be marketed is not identical to the formulation used in the toxicology studies (including the impurity profiles), has the sponsor clearly defined the differences and submitted reviewable supportive data (ie., adequate repeat studies using the marketed product and/or adequate justification for why such repetition would not be necessary)?			The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
7) Does the route of administration used in animal studies appear to be the same as the intended human exposure route? If not, has the sponsor submitted supportive data and/or an adequate scientific rationale to justify the alternative route?	X		

8) Has the proposed draft labeling been submitted? Are the appropriate sections for the product included and generally in accordance with 21 CFR 201.577? Is information available to express human dose multiples in either mg/m ² or comparative serum/plasma AUC levels?	x		
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ITEM	YES	NO	COMMENT
9) From a pharmacology/toxicology perspective, is this NDA fileable? If not, please state in item # 10 below why it is not.	x		The reviewer cannot comment on the item because there is no pharmacology & toxicology sections.
10) Reasons for refusal to file:			

Herman Rhee, Ph.D.
 Reviewing Pharmacologist

Karen Davis-Bruno, Ph.D.
 Supervisory Pharmacologist

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Herman Rhee
8/10/2006 12:47:06 PM
PHARMACOLOGIST

Karen Davis-Bruno
8/10/2006 01:00:28 PM
PHARMACOLOGIST
NDA filing