

Electronic Mail Message

Date: 4/17/00 3:47:44 PM
From: Jennifer Daly (BYRON_CHEMICAL@compuserve.com)
Subject: COMMENTS FOR ORALLY INHALED AND NASAL DRUG PRODUCTS SUBCOMMITTEE OF THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (MEETING: APRIL 26,2000 / 8:30AM TO 5:30PM)

April 17, 2000
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CENTER FOR DRUG EVALUATION AND RESEARCH (HFD-21)
FOOD & DRUG ADMINISTRATION
Attn: Ms. Kimberly Littleton
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Littleton:

RE: COMMENTS FOR ORALLY INHALED AND NASAL DRUG PRODUCTS
SUBCOMMITTEE OF THE ADVISORY COMMITTEE FOR
PHARMACEUTICAL SCIENCE
(MEETING: APRIL 26, 2000 / 8:30AM TO 5:30PM)

Unfortunately, we are unable to attend the referenced meeting, but would appreciate some insight to the following issues, perhaps resulting from that meeting.

1. Is there any significant advantage to submit an ANDA for CFC inhalers prior to submitting an ANDA for non-CFC inhalers, or at this time, is one preferred over the other by FDA?
2. For Excipients, does one need to analyze other propellant impurities in HFA 134a or HFA 227 or is a certificate from the supplier/manufacturer sufficient in this respect?
3. For specificity of analytical method, are there any guidelines/guidances currently available covering forced degradation on finished product for inhalation?
4. For leachables, is a study report/certificate from the component manufacturer acceptable on "Extractables from components", or must the applicant do this as well? If the must also do it, are there any guidelines/guidances currently available? Also, is it necessary to carry out extractables for DPI's (since the product is in the dry stage)?
5. For clinical trials, do we need to carry out clinical trials for drug product separately when used with actuator and with spacer?
6. For equipment calibration, can you provide some insight on calibration of Anderson's Cascade impactor, as no guidance is given in the USP or FDA guidance?

Any information you can provide would be greatly appreciated.

Thank you in advance for your kind reply.

Sincerely,

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