

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-211

STATISTICAL REVIEW(S)

NDA 21-211
Follistim® - AQ (follitropin beta injection)
Organon, Inc.

Statistical Review(s) and Memoranda

There is no clinical data submitted for this NDA so statistical review is not required.

Electronic Mail Message

Date: 2/8/00 5:34:00 PM
From: Lisa Kammerman (KAMMERMAN)
To: Eufrecina DeGuia (DEGUIAE)
Cc: Terri Rumble (RUMBLET)
Subject: Follistim AQ (21-211)

Freshnie,

I've looked over the statistical section of 21-211. There is no efficacy data for us to review. The information is all biopharm.

Therefore, a statistical review will not be done for this NDA.

Thanks,

Lisa

NDA 21-211
Follistim® - AQ (follitropin beta injection)
Organon, Inc.

Statistics review(s) and memoranda regarding dissolution and/or stability

Not applicable for this NDA.