Joint EMEA (NRG)/EFPIA Workshop

11 September 2006 in London

FDA Practices

Introduction

- **Rejection rate FDA (2005) = 35 – 40 %**
- **No written Guidelines**

  - But Guidances to be released in 2006 =

  . *Good Naming, Labeling and Packaging*

  . *Selecting and Submitting Proprietary Names for Evaluation*

Advance approval of Proprietary Names
Timing to submit

- **Possibility to submit up to 2 names (by order of preference) per NDA**
- **Review performed by FDA until one name is found acceptable**
- **FDA Review = timing not predictable**

  - submission as early as end of Phase II

  - target review cycle = 90 days

Advance approval of Proprietary Names Timing to submit

- **Final review of proprietary names = 90 days prior to the approval letter for the compound => risk of late rejection**

FDA Assessment process
Teams involved

- **Applicant submits request for proprietary name review to Reviewing Division**
- **Project manager at the Reviewing Division forwards the request to the Project Manager in DMETS (Division of Medication Errors and Technical Support) = in charge of proprietary names Safety Assessment**

FDA Assessment process
Teams involved

- **DMETS data collection process**
  - **Expert Panel Review**

    Chaired by DMETS staffer – 12 people

    . Composition :

    1. **DMETS Medication Errors Prevention Staff**
    2. **Representative from DDMAC (Division of Drug Marketing, Advertising and Communications) = in charge of Promotional Assessment (and misleading aspects)**

FDA Assessment process
Teams involved

. <u>Primary self-evaluation</u>

1. **Independent evaluation**
2. **Use of Orange Book, IMS Database, Merck Index, USPTO Database …**

FDA Assessment process
Teams involved

- **Use of <u>computer program</u> = <u>POCA</u>**

  (Phonetic and Orthographic Computer Analysis)

  - **Search for Look-alike / Sound Alike**
  - **Evaluation of orthographic and phonetic similarity of new proprietary names with the similarity of those contained in the database**

    (Orange Book and FDA proprietary databases)

FDA Assessment process
Teams involved

– **<u>Prescription simulations</u>**
  - **Oral and written prescription**
  - **Simulations involving 100 volunteers from the FDA staff (including pharmacists, physicians and nurses)**

FDA Assessment process
Teams involved

- **DMETS Safety Evaluator Risk Assessment**

  Safety Evaluator

  - **Takes the results of Expert Panel analysis, Poca analysis and Prescription simulations**
  - **Prepares a Recommendation (proprietary name acceptable / not acceptable)**
  - **After approval by DMETS Director, Recommendation (including DDMAC opinion) is sent to ODS (Office of Drug Safety) for review and if acceptable ODS will send it to the Reviewing Division**

FDA Assessment process
Teams involved

- **<u>Reviewing Division action</u>**
  - **Decision to accept or not to accept DMETS Recommendation**
  - **Decision forwarded to Applicant**

    (with potential grounds for rejection, if any)

FDA Assessment process
Teams involved

- **No submission of the proprietary names to WHO / Usan Council**

Criteria applied by the FDA

- **Proprietary name should <u>not be misleading</u>**

  (therapeutic or pharmaceutical connotations, composition of the product)

- **Proprietary name should <u>not contribute to potential confusion errors</u> with marketed, recently approved, pending and withdrawn proprietary names of other pharmaceutical products**

  - <u>Contributing factors</u> for name confusion = similar indications, same patient population, identical formulations, overlapping strengths, stores in the same areas

Criteria applied by the FDA

- **Proprietary name should <u>not be similar to INN</u> and should <u>not include the stem</u> of an INN in a stem position**

  - <u>Exception</u> for short stems of 2 or 3 letters

  (ex. : - ac)

- **<u>Modifiers</u> = *qualifiers or suffixes in the EU* currently permissible**

  Ex. : CIPRO® XR (Extended Release)

  ZOFRAN® ODT (Orally Disintegrating Tablets)

  WELLBUTRIN® SR (Sustained Release)

Criteria applied by the FDA

- **Proprietary names should <u>not be laudatory</u> or over promising (claims not accepted) unless substantiated by data**

- **No recognition of legal <u>trademark registration process</u>**

Industry / FDA dialogue

- **Good Naming Practices (GNPs)**

  = help in the names assessment

  Work in progress by PhRMA – Not yet approved by the FDA

  - Describes all necessary steps to obtain trademark registration

  (legal clearance, USPTO examination, opposition procedure)

  +

Industry / FDA dialogue

- Risk Assessment / Medication Errors Potential Analysis = not mandatory

  (Health care providers input – use of third party services mimicking DMETS process)

  . USA = 1 language / 1 territory

  . EU = 20 languages / 25 territories (+2 / +2) // different alphabets and scripts

  => Issue = interpretation of the results

Reconsideration Process

- **Applicant requests reconsideration to the Reviewing Division**
- **Applicant provides justification / arguments in writing to retain the rejected proprietary name**
- **Dialogue / Face to face meetings with Reviewing Division + DMETS**
- **Remedies = variations, new proprietary name or use of INN + Company Name**

Comparison of EMEA / FDA practice

Similarities

- **High Rejection rate**
- **Criteria applied in the names evaluation :**

  Names :

  – **Should not be misleading**
  – **Should not cause confusion (other proprietary names / INN)**
  – **Should not be promotional**
- **No recognition of legal trademark registration process**
- **Continuous dialogue with Industry**

Comparison of EMEA / FDA practice
Differences

EMEA

- Guidelines
- Possible submission of 3 names per MA
- Review of all names submitted
- Names submission : 12 to 4-6 months prior to submission date to MAA
- 30 days review cycle
- Final review of names prior to granting of MA : no specific timing

FDA

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- Possible submission of 2 names per NDA
- Review of names until 1 is found acceptable
- Names submission : end of Phase II
- Target review cycle : 90 days but effective duration = longer
- Final review of names : 90 days prior to final opinion

Comparison of EMEA / FDA practice
Differences

EMEA

- Names reviewed by NRG Group + Representatives of Member States + WHO + European Commission
- Final validation by CHMP
- No prescription simulation
- No use of phonetic and orthographic computer analysis

- Suffixes : usually not accepted
- No direct dialogue / face to face meeting with NRG

FDA

- Names reviewed solely within FDA (DMETS, DDMAC, ODS) -
  No external stakeholder
- Final validation by Reviewing Division
- Prescription simulations (oral + written)
- Use of phonetic and orthographic computer analysis

- Modifers : recommended
- Dialogue / face to face meetings with the Reviewing Division + DMETS

Thank you for your attention !