**Division of Anti-Infectives**

**Single Patient IND (SPIND) request form**

**All information requested must be provided in order to assess patient eligibility for SPIND for clofazimine**

Date of request:

Drug name: clofazimine

Name of investigator (sponsor):

Name of caller/requestor if other than investigator:

Sponsor information

Address:

Phone #:

Fax #:

Cell/Pager#:

E-mail:

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1. PATIENT INFORMATION
2. Patient Initials
3. Age (in years):
4. If pediatric patient, please provide weight:
5. Gender  Male  Female
6. Patient has previously received clofazimine therapy

Yes  No

If yes, specify dates (start and end, mm/dd/yy to mm/dd/yy)

      to

Dose (in mg/day):

Duration (in months):

Response (cure, improvement, relapse, failure):

Serious Adverse Event(s):

1. DESCRIPTION OF CLINICAL DISEASE FOR WHICH CLOFAZIMINE IS REQUESTED
   1. Site of infection
   2. Organism isolated 
      1. Specimen source:
      2. All dates of isolation
      3. Antimicrobial susceptibility (drugs tested and susceptibility report)

and date:

* 1. Current antimicrobial therapy(ies)
  2. Previous therapy(ies):  Yes  No

If Yes, specify the reason(s) for discontinuation for each individual drug      

If No, provide a rationale for using clofazimine for the treatment of this patient

* 1. Underlying co-morbid condition(s):

1. PROPOSED CLOFAZIMINE TREATMENT PLAN
   1. Proposed dose (mg/day)
   2. Proposed duration (months)
   3. Proposed plan/frequency of assessment to determine response to therapy
      1. Cultures/frequency:
      2. Radiology/frequency:
      3. Clinical signs and symptoms frequency:

Proposed criteria for discontinuation of clofazimine (check as many as applicable)

Demonstration of lack of efficacy

Describe criteria on the basis of which response of therapy or lack thereof, is determined

Intolerance/toxicity (specify nature of event)

Other (specify)

1. INSTITUTIONAL REVIEW BOARD

Use of an investigational drug requires approval by an Institutional Review Board (IRB) before administration of the drug (21CFR 56.103) and assurance of IRB review (21 CFR 312.66).

Sponsor’s Signature:

Date:

FOR FDA USE

Approving MO/Project Manager

Single Patient IND #:

Date issued: