

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### ***APPLICATION NUMBER:***

**008975Orig1s008**

***Trade Name:*** PURIFIED CORTROPHIN GEL

***Generic or Proper Name:*** (repository corticotropin injection USP)

***Sponsor:*** ANI Pharmaceuticals, Inc.

***Approval Date:*** October 29, 2021

***Indication:*** Purified Cortrophin Gel is indicated in the following disorders:

1. Rheumatic disorders:  
As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:  
Psoriatic arthritis.  
Reference ID: 4880561  
Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).  
Ankylosing spondylitis.  
Acute gouty arthritis.
2. Collagen diseases:  
During an exacerbation or as maintenance therapy in selected cases of:  
Systemic lupus erythematosus.  
Systemic dermatomyositis (polymyositis).
3. Dermatologic diseases:

Severe psoriasis.

4. Allergic states:

Atopic dermatitis.

Serum sickness.

5. Ophthalmic diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

Allergic conjunctivitis.

Keratitis.

Iritis and iridocyclitis.

Diffuse posterior uveitis and choroiditis.

Optic neuritis.

Chorioretinitis.

Anterior segment inflammation.

6. Respiratory diseases:

Symptomatic sarcoidosis.

7. Edematous states:

To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without

uremia of the idiopathic type or that due to lupus erythematosus.

8. Nervous system:

Acute exacerbations of multiple sclerosis.

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**APPROVAL LETTER**



NDA 008975/S-008

## SUPPLEMENT APPROVAL

ANI Pharmaceuticals, Inc.  
Attention: Ellen Connolly  
Vice President, Regulatory Affairs  
210 Main Street West  
Baudette, MN 56623

Dear Ms. Connolly:

Please refer to your supplemental new drug application (sNDA) dated June 29, 2021, received June 29, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for purified Cortrophin Gel (repository corticotrophin injection USP).

This Prior Approval sNDA provides for quality information and supporting data for reintroduction of the product in the US market.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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