DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
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Center for Medicaid and CHIP Services

AUG 0 6 2012

Michael Mulroy
Senior Vice President
General Counsel and Corporate Secretary
Questcor Pharmaceuticals, Inc.
1300 North Kellogg Drive, Suite D
Anaheim, CA 92807

Dear Mr. Mulroy:

Thank you for your letter regarding the request by Questcor Pharmaceuticals, Inc. (Questcor) for a new base date average manufacturer price (AMP) for the drug, Acthar Gel. As noted in your letter, the Food and Drug Administration (FDA) recently approved Acthar Gel for use in treating infantile spasms. It is your position in light of FDA's approval that Acthar is eligible for a new based date AMP.

We have reviewed your request and agree that Acthar Gel is eligible for a new base date AMP. Section 1927(c)(2)(A) defines the base date AMP, in part, for each single source or innovator multiple source drug approved by the FDA before or after October 1, 1990. In accordance with that provision, the base date AMP is calculated based on the new drug application which is approved by the FDA, not the national drug code (NDC). Therefore, given that the recently approved Acthar Gel was approved under a different NDC from the original product, Questcor may set a new base date AMP for this drug.

In your letter, you proposed two options with respect to the calculation of a new base date AMP. First, you note that based on the proposed rule, Questcor could revise its base date based on revisions in the Affordable Care Act. Second, you note that Questcor could create a new NDC-9 based on the recent FDA approval. For the purpose of the Medicaid Drug Rebate Program we believe the assignment of a new NDC-9 to the recently approved Acthar Gel would be necessary. We understand Questcor's concerns regarding how this option might create some confusion; however, the Centers for Medicare & Medicaid Services (CMS) does not have the current capability to allow a manufacturer to replace the original reported base date AMP with a new base date AMP midway through the life of a product. We request that Questcor notify CMS about the new NDC-9 and baseline data when Questcor has this information and is ready to report the information into the Drug Data Reporting for Medicaid system.

The decision in this letter is limited to and based on the facts and information presented to us and has no applicability to a different set of facts even if such facts appear similar in nature or in scope. Also, this letter is not, and may not be considered to be, an advisory opinion under section 1128D(b) of the Social Security Act, since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, this letter is not a release of liability.

If you have any questions or issues, please contact Meagan Khau at meagan.khau@cms.hhs.gov or 410-786-1357 for assistance.

Sincerely,

Cindy Mann
Director

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7500 Security Boulevard, Mail Stop S2-26 12
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Rec'd 9/27/12

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SEP 1 9 2012

Michael Mulroy
1300 N. Kellogg Drive, Suite D
Anaheim, CA 92807

Re: Base Date Average Manufacturer Price for Acthar® Gel

Dear Mr. Mulroy:

This letter is to provide a correction to the letter we sent you dated August 6, 2012. In that letter, we noted that given that Acthar Gel was approved under a different National Drug Code (NDC) from the original product, Questcor Pharmaceuticals may set a new base date AMP for this drug. This was a misstatement on our part. As noted in your letter of May 8, 2012, the FDA approved Acthar Gel through a New Drug Application (NDA) for use in treating the orphan condition of infantile spasms. Accordingly, we would like to correct our earlier reply to note that because Acthar was approved under a new NDA, Questor may set a new base date AMP. We apologize for any confusion.

The decision in this letter is limited to and based on the facts and information presented to us and has no applicability to a different set of facts even if such facts appear similar in nature or in scope. Also, this letter is not, and may not be considered to be, an advisory opinion under Section 1128D(b) of the Act, since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, this letter is not a release of liability.

If you have any questions or issues, please contact Meagan Khau at meagan.khau@cms.hhs.gov or 410-786-1357 for assistance.

Sincerely,

Cindy Mann
Director