DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDA 078321/S-003

PRIOR APPROVAL SUPPLEMENT APPROVAL

CSPC Pharmaceutical Group Ltd., International Division
U.S. Agent for CSPC Ouyi Pharmaceutical Co., Ltd.
4070 Truxel Road
Sacramento, CA 95834
Attention: Qingxi Wang
U.S. Regulatory Agent

Dear Sir:

Please refer to your supplemental Abbreviated New Drug Application (sANDA) dated April 17, 2015, received April 17, 2015, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your Abbreviated New Drug Application (ANDA) for Metformin Hydrochloride Extended-release Tablets USP, 500 mg and 750 mg.

Reference is also made to the complete response letter issued by this office on February 12, 2016, and to your amendments dated February 19, and April 28, 2016.

The supplemental ANDA, submitted as "Prior Approval Supplement," provides for:

- Addition of CSPC Ouyi Pharmaceutical as an alternative manufacturing facility.
- Addition of Shouguang Fukang Pharmaceutical as an alternate source of the Active Pharmaceutical Ingredient (API) Metformin Hydrochloride USP drug substance (DMF#23273).

We have completed our review of this sANDA, as amended, and it is **approved**.

We remind you that you must comply with the requirements for the approved ANDA described in 21 CFR 314.80-81.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not

met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2016.05.12 14:59:45 -04'00'

For Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research