DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DMF 038124

DMF ACKNOWLEDGEMENT

BEIJING T&L BIOLOGICAL TECHNOLOGY CO., LTD.
ATTENTION: LIYAN WANG, CEO
ROOM 822-2, 8 FLOOR, BUILDING 1
NO. 18, YANG FANG DIAN ROAD, HAIDIAN DISTRICT
BEIJING, 100089, P.R., CHINA

Dear Liyan Wang,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED:	038124
DATE OF SUBMISSION:	APRIL 25, 2023
DMF TYPE:	II
SUBJECT (TITLE):	ANTI-HUMAN CD3/CD28 BEADS FOR T CELL
HOLDER:	BEIJING T&L BIOLOGICAL TECHNOLOGY CO., LTD.
SUBMITTED BY:	BEIJING T&L BIOLOGICAL TECHNOLOGY CO., LTD.
AGENT:	SHIJIAZHUANG CREADY PHARMACEUTICAL R AND D INC.

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs

The holder of the DMF is responsible for compliance with 21 CFR314.420 as interpreted in "The Guideline for Drug Master Files" at https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
    a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF (with DMF number) is also not sufficient to authorize that party to reference the DMF.
    b. Any change, addition or deletion of information
    c. Annual Reports to the DMF containing:
        i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
        ii. A complete list of all parties currently authorized to incorporate information in the DMF by reference; identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
        iii. A list of all parties whose authorization has been withdrawn, if applicable.
        iv. Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Submissions that are over 10GB may be submitted on physical media (such as compact disc) to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

See FDA eCTD Web Page[1] and Guidance for Industry on electronic submissions[2] for information.

[1] See FDA eCTD Web Page for further information. https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

[2] Section 745A(a) of the Food, Drug, and Cosmetic Act. See "Guidance for Industry: Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (April 2017). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0

For question on DMF submissions, send an email to dmfquestion@fda.hhs.gov

Sincerely,
{See appended electronic signature page}
Vathsala Selvam
Drug Master File
Division of Life Cycle API/ONDP/OPQ
Center for Drug Evaluation and Research
Food and Drug Administration

CC:
SHIJIAZHUANG CREADY PHARMACEUTICAL R AND D INC.
ATTENTION : MR. KOU GUOTONG
ROOM 1703, BUILDING B, NO. 319 XIANGJIANG ROAD
GAOXIN DISTRICT, SHIJIAZHUANG CITY
HEBEI PROVINCE, 050000, P.R., CHINA

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CLAUDE THEOPHIN
05/01/2023 09:28:02 AM