DMF filing summary

Two Type II Drug Master Files on record with the US FDA

DMF 038124	DMF 038820	TYPE	STATUS
ActSep CD3/CD28 beads	**Anti-human CD28 mAb**	**II - drug substance / excipient**	**Active**

WHAT A DMF ALLOWS

A Type II DMF is a submission to the FDA containing confidential manufacturing information for a material used in a drug product. It is not approved or rejected - it is reviewed only when a sponsor references it in their own filing. The value to a sponsor is that the chemistry, manufacturing and controls detail is already on file, so the material can be referenced in an IND without duplicating that work.

FILES ON RECORD

Reference	Material	Coverage	Status
038124	ActSep CD3/CD28 separation and activation beads	Manufacture, release testing, stability	Active
038820	Anti-human CD28 monoclonal antibody	Manufacture, release testing, stability	Active

HOW TO REFERENCE A FILE

- Request a letter of authorisation naming your company and the file number.
- We issue the letter to the file holder of record within five business days.
- Your regulatory team submits the letter with the reference in your IND or BLA.
- We answer FDA information requests directly; the file content stays confidential.

SCOPE AND LIMITS

The files cover the materials as manufactured at our Carlsbad facility under the current process. A change of manufacturing site, scale or process triggers an annual report or an amendment, and sponsors referencing the file are notified where the change is relevant to their application.

This summary is a communication aid, not the filing itself. The file content is confidential and is released to the agency, not to sponsors.