IND 972109

Request for Information

Atos-Syntel

Attention: Jonathon Arbuckle

Senior Associate Director, Division of Imaging and Radiation (DIRM)

FDA/CDER

Building No.4, Mindspace, Thane-Belapur Road, MIDC INDL Area

Airoli, Navi Mumbai, Maharashtra 400708

Dear Dr.Arbuckle:

Please refer to your investigational new drug application (IND) submitted under section 505 of the Federal Food, Drug and Cosmetic Act for xxxxxx

We also refer to your amendment(s) dated October 26, 2022; November 13, 2022;

December 9, 2022; December 16, 2022 and January 12, 2023.

We have the following comments and requests for additional information. Please note that these requests are not clinical hold issues. However, response to them is requested:

Item#1:

Based on your submitted protocol CO-0000-001 and XXXXXXX Sub-protocol, it appears that you are pursuing a pathway intended to leverage XYXYXYXY investigation in support of new patient selection indication for XXXXXXXX. In approaching the design of downstream studies, we recommend that you focus on at least the following four high level considerations:

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Sincerely,

Magnus Carlsen

2/21/2023 1:21:42 PM

Libo M., MD, PhD

Director

Division of Imaging and Radiation Medicine

Office of Specialty Medicine

Center for Drug Evaluation and Research