Cytiva
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To whom it may concern

Regarding: Nitrosamines in cell culture products

Nitrosamines have become a concern for API and finished human drug manufacturers as evidenced by the following:

EMA finalized a review under Article 5(3) of Regulation (EC) No 726/2004 in June 2020 to provide guidance to marketing authorization holders on how to avoid presence of nitrosamine impurities in human medicines. Assessment report EMA/369136/2020 "*Nitrosamine impurities in human medicinal products*" as adopted by the CHMP was published on 25 June 2020.

FDA Guidance for Industry "*Control of Nitrosamine Impurities in Human Drugs*" published in September 2020 recommends steps manufacturers of APIs and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

Cytiva does not manufacturer APIs or finished human drugs but understands that cell culture products may be used in the manufacture of finished drugs and drug products.

A key source of nitrosamine contamination is sodium nitrite.

It is hereby stated that nitrite salts, including sodium nitrite, are not primary raw materials in cell culture products, nor are they intentionally added or introduced during manufacture of these products.

Cytiva assures that raw materials conform to specified requirements and are acquired from qualified suppliers; however, information has not been secured from all component suppliers to address any contamination risks that may be present.

Specific analytical testing for nitrosamines and nitrosamine-related materials is not performed on raw materials or Cytiva finished goods.

Signature: 	Date: 11 February 2021
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