



PS-44—2016

REAFFIRMED 2022

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POSITION STATEMENT

DESIGNATED MEDICAL GASES ARE NOT ACTIVE PHARMACEUTICAL INGREDIENTS

Question

Are designated medical gases ever considered active pharmaceutical ingredients (API) by the U.S. Food and Drug Administration (FDA)? Are manufacturers' of designated medical gases required to register their facilities as API manufacturers and list their products as APIs with the FDA for either human or animal drug use?

Answer

No, a designated medical gas is never considered an API. This is based on the Compressed Gas Association's (CGA) review of the *Food, Drug, and Cosmetic Act* requirements for APIs, FDA's 2001 Guidance document, *Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* and the intent of U.S. Congress when approving designated medical gases as part of the *Food and Drug Administration Safety and Innovation Act* (FDASIA) [1, 2, 3]. The third paragraph in the Scope of Q7A API Guidance excludes medical gases and other bulk packaged drug products [2]. This exclusion is consistent with the historic treatment of medical gases (since the early 1980's) only as finished pharmaceuticals and not APIs for either humans or animals.

Background

In April 2014, FDA personnel involved with Animal Drug listing indicated that any facility that had a designated medical gas listed that would be used by animals, must identify their source, if not the original manufacture of the designated medical gas and then the original manufacturer must register and list as an API manufacturer.

In addition, pharmaceutical manufacturers have requested that designated medical gas manufacturers provide them with information as to the API status of designated medical gases that these medical gas manufacturers provide to pharmaceutical manufacturers for their manufacturing operations.

CGA contacted the FDA in regards to this issue and received a response on May 9, 2014 communicating that, "Incoming animal drug product Structured Product Labeling (SPL) documents will be adjusted to no longer request the inclusion of the identity of the API manufacturer in animal drug product SPL files with an active ingredient, which is considered to be associated with a designated medical gas as described FDASIA."

Therefore manufacturers of designated medical gases are not required to register their facilities as API manufacturers and list their products as APIs.

References

Unless otherwise specified, the latest edition shall apply.

[1] *Food, Drug, and Cosmetic Act*, U.S. Food and Drug Administration. www.fda.gov

[2] *Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*, U.S. Food and Drug Administration. www.fda.gov

[3] *Food and Drug Administration Safety and Innovation Act*, Superintendent of Documents, U.S. Government Printing Office. www.gpo.gov

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Work Item 22-028
Medical Gases Committee

NOTE—No technical information has been changed from the 2016 edition. This reaffirmed edition may include minor editorial changes.

READFFIRMED: 2022
FIRST EDITION: 2016

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