

**AUTHORITY FOR ADVANCE RULING
GOODS AND SERVICE TAX
UTTAR PRADESH
4, VibhutiKhand, Gomti Nagar, Lucknow-**

ADVANCE RULING NO. UP ADRG 32 /2023/ DATED 01-09 -2023

PRESENT:

1. Shri Amit Kumar

Joint Commissioner, Central Goods and Service Tax
Audit Commissionerate, Lucknow
(Central Tax)

.....Member

2. Shri Harilal Prajapati

Joint Commissioner, State Goods and Service Tax
(Tax)

.....Member (State)

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|----|---|--|
| 1. | Name and address of the Applicant | M/sIBA Molecular Imaging (India) P. Ltd.,having registered office at D-131, Sector-63 Noida, Gautam Buddha Nagar, Uttar Pradesh – 201301 |
| 2. | GSTIN or User ID | 09AABCI3249R1ZZ |
| 3. | Date of filing of Form GST ARA-01 | 01.06.2023 |
| 4. | Represented by | Susamoy Mishra, Ravi Goyal and Shubham Madaan |
| 5. | Jurisdictional Authority-Centre | Range-12, Division-Division III Noida, Commissionerate-Noida |
| 6. | Jurisdictional Authority-State | Sector- Noida Sector -10, Range-Gautam Buddha Nagar (B), Zone-Gautam Buddha Nagar, Uttar Pradesh |
| 7. | Whether the payment of fees discharged and if yes, the amount CIN | Yes UTIB23060900006843 |

**ORDER UNDER SECTION 98(4) OF THE CGST ACT, 2017
& UNDER SECTION 98 (4) OF THE UPGST ACT, 2017**

M/s IBA Molecular Imaging (India) P. Ltd., having registered office at D-131, Sector-63 Noida, Gautam Buddha Nagar, Uttar Pradesh – 201301 (hereinafter referred as "the applicant") having GSTIN-09AABCI3249R1ZZ, have filed an application for Advance Ruling under Section 97 of the CGST Act, 2017 read with Rule 104 of the CGST Rules, 2017 and Section 97 of UPGST Act, 2017 read with Rule 104 of the UPGST Rules, 2017 in form GST ARA-01 (the application form for Advance Ruling), discharging the fee of Rs. 5,000/- each under the CGST Act and the UPGST Act.

2. The applicant is, registered under the provisions of Central Goods and Services Tax Act, 2017 as well as Uttar Pradesh Goods and Services Tax Act, 2017 (herein after referred to as the CGST Act and UPGST Act respectively). The applicant is engaged in the manufacture of pioneer drugs labelled as 18F-Fluorodeoxyglucose, 18F PSMA, 18 F DOPA and many more Radioactive compounds labelled with F 18. F18 compound are Radioactive isotopes, used as diagnostic reagent, used primarily for diagnosis of cancer. It is also used in cardiology and neurology. As per the applicant, the above mentioned product is classifiable under chapter heading 3006 of the HSN, leviable to GST @ 12% (CGST and SGST both @ 6% each), in terms of entry No 65 of Schedule II of the Notification No 01/2017-CT (Rate), dated 28.06.2017 read with corresponding rate notification issued under UPGST Act, 2017.

3. The applicant has sought advance ruling in respect of the following questions:

- i) Whether the F-18 Products would be classified under HSN 30063000, leviable to GST at the rate of 12%, in terms of entry no 65 of Schedule II of the Notification No 01/2017, Central Tax (Rate) issued under Central Goods and services Tax Act, 2017 (CGST Act, 2017) read with corresponding rate notification issued under the provisions of Uttar Pradesh Goods and Services Tax Act (UPGST) Act, 2017, or not?
- ii) If not, what would be the HSN classification and rate of tax applicable on the product under consideration.

4. The question is about classification of goods under the provisions of CGST Act and liability to pay GST, hence is admissible under Section 97(2)(a) of the CGST Act 2017. Further, as per declaration given by the applicant in Form ARA-01, the issue raised by the applicant is neither pending nor decided in any proceedings under any of the provisions of the Act, against the applicant.

5. Statement of relevant facts having a bearing on the question(s) raised

The applicant is, registered under the provisions of Central Goods and Services Tax Act, 2017 as well as Uttar Pradesh Goods and Services Tax Act, 2017 (herein after referred to as the CGST Act and UPGST Act respectively). The applicant is engaged in the manufacture of pioneer drugs labelled as 18F-Fluorodeoxyglucose, 18F PSMA, 18 F DOPA and many more Radioactive compounds labelled with F 18. F18 compound are Radioactive isotopes, used as diagnostic reagent, used primarily for diagnosis of cancer. It is also used in cardiology and neurology. As per the applicant, the above mentioned product is classifiable under chapter heading 3006 of the HSN, leviable to GST @ 12%

(CGST and SGST both @ 6% each), in terms of entry No 65 of Schedule II of the Notification No 01/2017-CT (Rate), dated 28.06.2017 read with corresponding rate notification issued under UPGST Act, 2017.

6. The applicant has submitted their interpretation of law as under-

- The classification of goods for the purpose of GST is to be undertaken using the general rules of interpretation of the First Schedule of the Customs Tariff Act, including the Section and chapter Notes and the General Explanatory Notes of the First Schedule of the Customs Tariff Act to the extent they are relevant.

- 'FDG/F-18' is not specifically mentioned in the Rate tariff. F-18 compounds are diagnostic reagent primarily used for diagnosis of cancer.

- F-18 products having pharmaceutical use shall merit classification under chapter 30 and Note 4 to chapter 30 specifies that 'Heading 3006 applies only to the following, which are to be classified in that heading and in no other heading of this schedule' wherein sub heading (d) to note 4 stipulates

'(d) opacifying preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed together for such uses;'

Sub heading 30063000 covers the diagnostic reagents designed to be administered to the patient. Since the term reagent has not been defined in the Tariff, they have placed reliance upon various dictionary definitions.

- In the applicant's case FDG/F-18 compounds are synthesized through a chemical process and is used to detect and visualize metabolic activity in various organs and tissues in the human body. FDG is administered to patients as an injectable solution, and it is taken up by cells in the body that require glucose for energy.

- The Diagnostic Reagents not designed to be administered on a patient are excluded from the chapter 30 as per the explanatory notes. However the applicant's products are diagnostic reagents which are administered to the patients, the same will fall under tariff heading 30063000.

- Classification of product to be done according to entry providing the most specific description. Further it has been held by various judicial forums that if classification is possible based on headings then no need to go by section note or chapter note.

- Similar product imported by the appellant, 'Technitium 99M (TC99M) Life saving perishable Goods (Radioactive) 12 GBQ' having similar use has been classified under 3006300 while filing the Bill of entry, which has been accepted by the Customs authorities. Hence the same needs to be adopted for GST also.

- Based on above, the applicant has submitted that all their F-18 products are classifiable under tariff item 30063000 as diagnostic reagents

designed to be administered to the patient and attracts GST @ 12% under entry no 65 of Schedule II to notification no 01/2017-CT(R).

7. The application for advance ruling was forwarded to the Central Jurisdictional GST Officer vide letter dated 19.06.2023 to offer their comments/views/verification report on the matter.

Deputy Commissioner, SGST- Sector 10, Noida has submitted his comments vide his letter dated 24.06.2023 wherein it has been submitted that since the HSN code 28444000 specifies the products, **'Radioactive Chemical elements and Radioactive Isotopes (including the Fissile or Fertile Chemical Elements and Isotopes) and their compounds; Mixtures and Residues containing these products radioactive elements and isotopes'** and HSN Code 30063000 specifies the products **'Pharmaceutical Goods specified in Note 4 to this chapter Opacifying Preparations for X-Ray Examinations; Diagnostic Reagents designed to be administered to the patient.'** The applicant's product is Radioactive injection which is classifiable under HSN 28444000 chargeable to GST @ 18%.

8. Mr. Shubham Madaan, Mr Ravi Goyal and Mr Susamoy Mishra, Authorized representatives of the applicant appeared for the personal hearing held on 03.07.2023 and reiterated the submissions made in the application of advance ruling.

8.1 The applicant filed additional submissions wherein they submitted the following documents certifying the medical use of their product:-

- i) Certificate of Board of Radiation and Isotope Technology
- ii) Letter on use by Head of Radiation medicine center
- iii) Letter on use by various renowned doctors
- iv) FDG use as per various articles published in Journals and scientific literature

DISCUSSION AND FINDING

9. At the outset, we would like to make it clear that the provisions of both the CGST Act and the UPGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to such dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provision under the UPGST Act. Further to the earlier, henceforth for the purposes of this Advance Ruling, a reference to such a similar provision under the CGST Act / UPGST Act would be mentioned as being under the 'CGST Act'.

10. We have gone through the submissions made by the applicant and have examined the interpretation submitted by them. At the outset, we find that the

issue raised in the application is squarely covered under Section 97(2)(a) of the CGST Act 2017 being a matter related to classification of goods under the provisions of this Act. We therefore, admit the application for consideration on merits.

11. The applicant is engaged in the manufacture of pioneer drugs labelled as 18F-Fluorodeoxyglucose, 18F PSMA, 18 F DOPA and many more Radioactive compounds labelled with F 18. F18 compound are Radioactive isotopes, used as diagnostic reagent, used primarily for diagnosis of cancer. It is also used in cardiology and neurology. As per the applicant, the above mentioned product is classifiable under chapter heading 3006 of the HSN, leviable to GST @ 12% (CGST and SGST both @ 6% each), in terms of entry No 65 of Schedule II of the Notification No 01/2017-CT (Rate), dated 28.06.2017 read with corresponding rate notification issued under UPGST Act, 2017.

12. The applicant in the present application has sought advance ruling on following question/clarification-

- i) Whether the F-18 Products would be classified under HSN 30063000, leviable to GST at the rate of 12%, in terms of entry no 65 of Schedule II of the Notification No 01/2017, Central Tax (Rate) issued under Central Goods and services Tax Act, 2017 (CGST Act, 2017) read with corresponding rate notification issued under the provisions of Uttar Pradesh Goods and Services Tax Act (UPGST) Act, 2017, or not?
- ii) If not, what would be the HSN classification and rate of tax applicable on the product under consideration.

13. From the submissions made by the applicant, we observe that the applicant is engaged in the manufacture of various F-18 Compounds which are Radioactive isotopes used as diagnostic reagent, used primarily for diagnosis of cancer. It is also used in cardiology and neurology. Diagnostic Reagents are chemicals used in laboratories to determine specific types of pathogens, metabolic abnormalities, physiological anomalies and genetic disease. They can be used in vivo or in vitro in order to detect certain disease. It is seen that these chemicals may either be used externally or administered to a patient for diagnosis of various diseases.

14. According to Wikipedia, the free encyclopedia, **Fluorine-18** (¹⁸F) is a fluorine radioisotope which is an important source of positrons. **FDG**, is a radiopharmaceutical, specifically a radiotracer, used in the medical imaging modality positron emission tomography (PET).

14.1 The applicants have submitted at length that their product is specifically used by the pharmaceutical industry for medical use only. They have submitted

various documents in support of their claim. It has been submitted that for classification of goods, the predominant use of the goods is very relevant and important.

15. However, it can be seen that F-18 products are essentially radioactive isotopes which are used in radiopharmaceutical imaging such as PET scanning. Although they are used as a pharmaceutical product for the diagnosis and detection of various diseases, ¹⁸F FDG and other ¹⁸F radiopharmaceutical products are compounds of the radioisotope ¹⁸F. Heading 2844 of the Tariff covers radioactive isotopes and their compounds. ¹⁸F-FDG being a compound of the radioisotope ¹⁸F, it would fall under the heading 2844. In order to arrive at the correct classification of the product, it is necessary to consider the General Rules for interpretation of the tariff wherein Rule 1 provides that:-

**GENERAL RULES FOR THE INTERPRETATION OF THE HARMONIZED
SYSTEM**

“Classification of goods in the Nomenclature shall be governed by the following principles:

1. The titles of Sections, Chapters and sub-Chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings **and** any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following provisions :

Hence the Section or Chapter Notes have to be considered before deciding the classification of any product. Products of Chemicals and allied industries are covered under Section VI of the Tariff and the Section Notes provide as follows :

SECTION VI-PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES NOTES

1. (A) **Goods (other than radioactive ores) answering to a description in heading 28.44 or 28.45 are to be classified in those headings and in no other heading of the Nomenclature.**
(B) Subject to paragraph (A) above, goods answering to a description in heading 28.43, 28.46 or 28.52 are to be classified in those headings and in no other heading of this Section.
2. **Subject to Note 1 above**, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.

15.1 Hence in view of the provisions contained in paragraph 1(A) of this Note, all radioactive chemical elements and radioactive isotopes, and compounds of such elements and isotopes (whether inorganic or organic, and whether or not chemically defined), are classified under heading 28.44, even though they could also fall under some other heading of the Nomenclature.

Paragraph 1(B) of the Note provides that goods described in heading 28.43, 28.46 or 28.52 are to be classified under whichever of those headings of those headings is appropriate and under no other heading in Section VI, provided they are not radioactive or in the form of isotopes (in which case they are classified in either heading 28.44 or heading 28.45).

15.2 Section Note 2 provides that goods **(other than those described in heading 28.43 to 28.46 or 28.52)** which are covered by heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37. 07 or 38.08 **by reason of being put up in measured doses or for retail sale, are to be classified in those headings notwithstanding that they could also fall in some other heading of the Nomenclature.**

The appellant has submitted that the product in question being diagnostic reagents to be administered to the patients, merit classification under heading 3006. *"Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient"*

Diagnostic reagents are chemicals used in laboratories to determine specific types of pathogens, metabolic abnormalities, physiological anomalies, and genetic diseases. They're relied upon by medical practitioners to make accurate diagnoses, and can be used in vivo or in vitro in order to detect certain diseases.

However, it is observed that the Section Note 1(A) specially stipulates that Goods answering to a description in heading 2844 are to be classified in the said heading only. F18 is a radioisotope and Fluorodeoxyglucose (18F-FDG) is a compound. The products being radioactive and compound of the radioisotope 18F, the same merits classification under heading 2844 only although it satisfies the condition mentioned in Chapter 30 i.e diagnostic reagent designed to be administered to the patient. The applicant has also submitted that medicaments are covered under Tariff heading 30 and that the same product has been classified under heading 3006 by some supplies. However, it may be appreciated that the classification of goods are to be guided by the provisions of law and Radioactive chemicals elements and radioactive isotopes are classifiable under ChSh 2844 only and nowhere else.

16. In view of the above discussions, we, both the members unanimously rule as under;

RULING

- i) Whether the F-18 Products would be classified under HSN 30063000, leviable to GST at the rate of 12%, in terms of entry no 65 of Schedule II of the Notification No 01/2017, Central Tax (Rate) issued under Central Goods and services Tax Act, 2017 (CGST Act, 2017) read with


corresponding rate notification issued under the provisions of Uttar Pradesh Goods and Services Tax Act (UPGST) Act, 2017, or not?

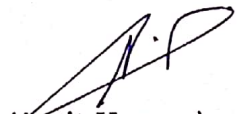
Answer: In negative

ii) If not, what would be the HSN classification and rate of tax applicable on the product under consideration.

Answer: 2844 @ 18% (9% CGST + 9% SGST)

17. This ruling is valid only within the jurisdiction of Authority for Advance Ruling Uttar Pradesh and subject to the provisions under Section 103(2) of the CGST Act, 2017 until and unless declared void under Section 104(1) of the Act.


(Harilal Prajapati)
Member of Authority for Advance Ruling


(Amit Kumar)
Member of Authority for Advance Ruling

To,

M/s IBA Molecular Imaging (India) P. Ltd.,
D-131, Sector-63 Noida,
Gautam Buddha Nagar,
Uttar Pradesh – 201301

AUTHORITY FOR ADVANCE RULING –UTTAR PRADESH

Copy to –

1. The Chief Commissioner, CGST & Central Excise, Lucknow, Member, Appellate Authority of Advance Ruling.
2. The Commissioner, Commercial Tax, Uttar Pradesh, Member, Appellate Authority of Advance Ruling.
3. The Commissioner, CGST & Central Excise, C-56/42, Sector-62, Noida-201309.
4. The Deputy/Assistant Commissioner, CGST & Central Excise Division-III Noida, GST, C-56/42, Sector-62, Noida-201309.
5. Through the Additional Commissioner, Gr-I, Commercial Tax, G.B.Nagar....., Uttar Pradesh to jurisdictional tax assessing officers.

Note: An Appeal against this advance ruling order lies before the Uttar Pradesh Appellate Authority for Advance Ruling for Goods and Service Tax, 4, Vibhuti Khand, Gomti Nagar, Lucknow – 226010, within 30 days from the date of service of this order.