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Tender

Provision of Regulatory Affairs services to support with obtaining Marketing Authorisation from the VMD for Cattle BCG and a companion skin test, DST-F

Defra Network eTendering Portal

F02: Contract notice

Notice identifier: 2021/S 000-028008

Procurement identifier (OCID): ocids-h6vhtk-02d32b

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Section I: Contracting authority

I.1) Name and addresses

Defra Network eTendering Portal

17 Nobel House

London

SW1P 3JR

Email

colette.newton@defra.gov.uk

Telephone

+44 2072385921

Country

United Kingdom

NUTS code

UK - United Kingdom

Internet address(es)

Main address

www.defra.gov.uk

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

<https://defra.bravosolution.co.uk>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://defra.bravosolution.co.uk>

Tenders or requests to participate must be submitted to the above-mentioned address

I.4) Type of the contracting authority

Ministry or any other national or federal authority

I.5) Main activity

Environment

Section II: Object**II.1) Scope of the procurement****II.1.1) Title**

Provision of Regulatory Affairs services to support with obtaining Marketing Authorisation from the VMD for Cattle BCG and a companion skin test, DST-F

Reference number

33135

II.1.2) Main CPV code

- 71356000 - Technical services

II.1.3) Type of contract

Services

II.1.4) Short description

Provision of regulatory affairs services for compilation and submission to the UK Veterinary Medicines Directorate of Marketing Authorisation Dossiers for CattleBCG and DST-F as part of the of the UK Government bovine tuberculosis (bTB) eradication programme.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 71356300 - Technical support services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

APHA is seeking a contractor for provision of regulatory services for immunological veterinary medicinal products (IVMPs) to compile two Marketing Authorisation (MA) dossiers and manage the MA submissions CattleBCG and DST-F, a DIVA skin test classified as an IVMP for regulatory purposes.

The contractor will be responsible for collating all relevant documentation and parts of the dossier submission to include summary of the dossier, product quality, safety and efficacy data and bibliographic references. Compiling the dossiers according to the requirements outlined in EurdraLex- Volume 6B & 6C and any additional requirements laid down by the Veterinary Medicines Directorate (VMD) for the content and structure of the dossiers

Services are expected to commence from February 2022, please refer to tender document for more information on service commencement date.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months

36

This contract is subject to renewal

Yes

Description of renewals

Optional 12 month extension. No further renewals expected after this.

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

II.2.14) Additional information

A PIN was issued earlier this year is to alert the market to this opportunity and invited interested parties to download the supplier information pack which has further information on this project.

This supplier information pack can be downloaded from Bravo along with the full tender documents.

Section III. Legal, economic, financial and technical information

III.1) Conditions for participation

III.1.1) Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions

Please refer to tender documents

III.1.2) Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3) Technical and professional ability

Selection criteria as stated in the procurement documents

III.2) Conditions related to the contract

III.2.2) Contract performance conditions

Please refer to tender documents

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.1) Previous publication concerning this procedure

Notice number: [2021/S 000-019388](#)

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

9 December 2021

Local time

12:00pm

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.6) Minimum time frame during which the tenderer must maintain the tender

Duration in months: 4 (from the date stated for receipt of tender)

IV.2.7) Conditions for opening of tenders

Date

9 December 2021

Local time

12:00pm

Information about authorised persons and opening procedure

Sealed Parallel Opening of Tender Documents via Bravo e-Tendering System

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.4) Procedures for review

VI.4.1) Review body

Defra

London

SW1P 3JR

Country

United Kingdom