

APPENDIX 24

APPEAL

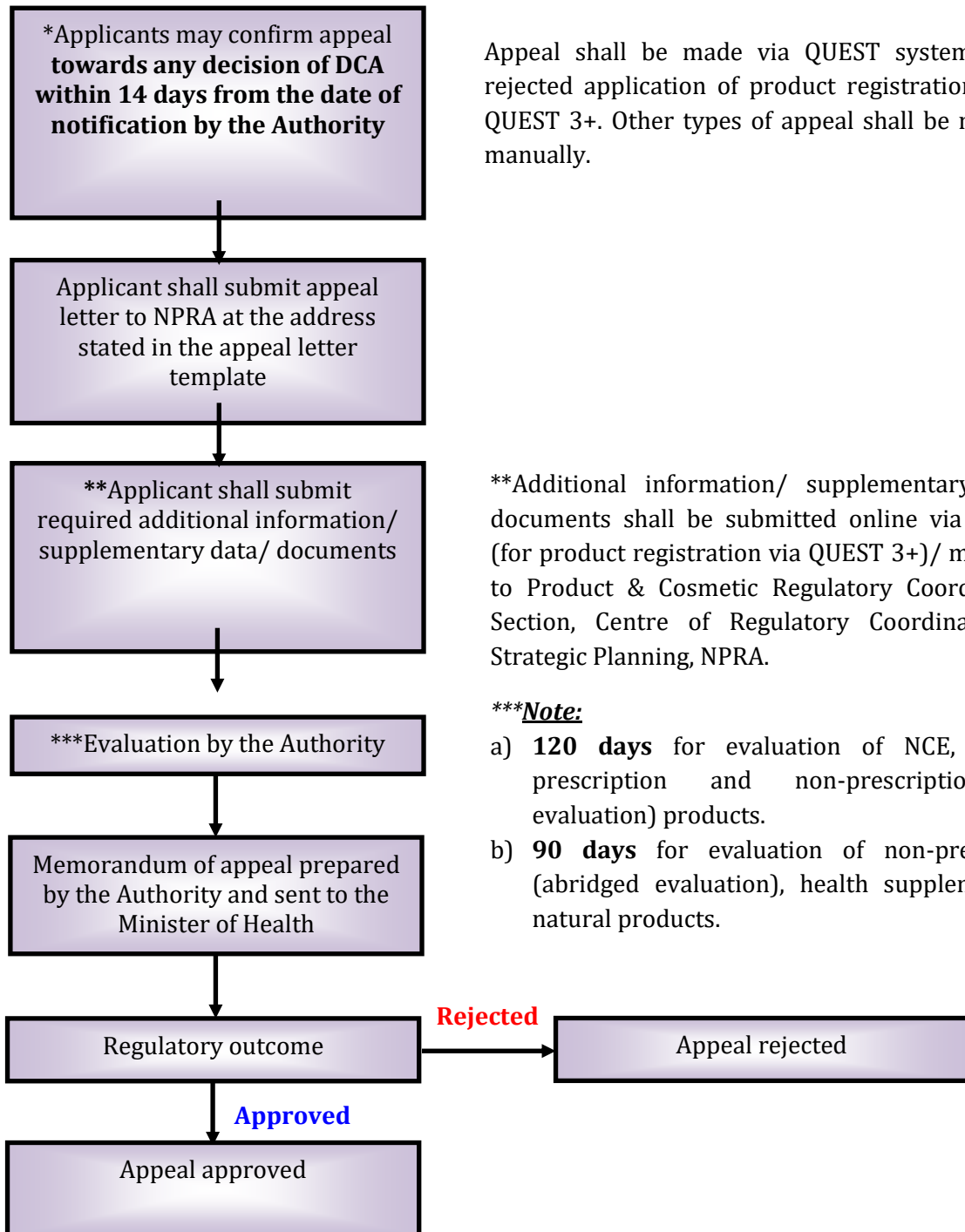
As stipulated under Regulation 18, CDCR 1984, any person aggrieved by the decision of the Authority or the Director of Pharmaceutical Services, may make a written appeal to the Minister of Health Malaysia.

All notice of appeals shall be made **within fourteen (14) days** from the date of notification by the Authority;

- A period of 60 days from the date of appeal confirmation is given for submission of any additional information/ supplementary data/ documents for all product categories.
- The appeal shall not be considered if all the required information is not submitted within the specified time frame given. **Any request for extension of this period shall not be considered.**
- Any decision of the Minister made on an appeal shall be final.

The appeal for rejected applications of product registration shall be submitted via the online QUEST system ONLY. Other types of appeal shall may be submitted manually.

THE PROCESS OF APPEAL



Appeal shall be made via QUEST system for rejected application of product registration via QUEST 3+. Other types of appeal shall be made manually.

**Additional information/ supplementary data/ documents shall be submitted online via QUEST (for product registration via QUEST 3+)/ manually to Product & Cosmetic Regulatory Coordination Section, Centre of Regulatory Coordination & Strategic Planning, NPRA.

*****Note:**

- a) **120 days** for evaluation of NCE, Biologic, prescription and non-prescription (full evaluation) products.
- b) **90 days** for evaluation of non-prescription (abridged evaluation), health supplement and natural products.

TEMPLATE FOR AN APPEAL LETTER

LETTERHEAD SYARIKAT PEMEGANG PENDAFTARAN PRODUK

Nama dan alamat pemegang

Tarikh:

Y. B. Menteri Kesihatan Malaysia
d/a Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia
Lot 36, Jalan Universiti,
46200 Petaling Jaya
(u.p. Setiausaha PBKD)

Y. B.,

PERATURAN 18 – RAYUAN TERHADAP PENOLAKAN PERMOHONAN PENDAFTARAN

NAMA PRODUK : Sila nyatakan nama produk (*Please state the product name*)
NO. RUJUKAN : Sila nyatakan nombor pendaftaran produk
(*Please state the product reference number*)

Dengan segala hormatnya, pihak kami ingin membuat rayuan terhadap penolakan permohonan produk seperti di atas.

2. Alasan – alasan rayuan serta data tambahan/ maklumat akan dihantar kepada pihak Y.B. dalam tempoh 60 hari dari tarikh pengesahan penerimaan rayuan oleh pihak Y.B.

Sekian, terima kasih.

Yang benar,

Tandatangan Wakil Pemegang

(NAMA WAKIL PEMEGANG)

Jawatan Wakil Pemegang