RWANDA FDA
Rwanda Food and Drugs Authority

Rwanda Food and Drugs Authority
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QMS N°: FDISM/PVSM/FMT/034
Revision No: 0
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GUHAGARIKA IMUTI

Ref. No.: FDISM/PVSM/..2326../FDA/20.23

Abinjiza imiti mu Rwanda (Bose)
Abaranguza imiti (Bose)
Amavuriro ya Leta n'ayigenga (Yose)
Abadandaza imiti (Bose)
Abaganga n'abahanga mu by'imiti (Bose)

<u>Title:</u> Guhagarika ikwirakwizwa, ikoreshwa no kwinjiza mu gihugu umuti witwa Gastro resistant Sodium valproate 500mg na Gastro resistant Sodium valproate 300 mg y'ibinini ikorwa n'uruganda rwitwa 4Care Lifescience Pvt Ltd/ mu Buhinde

<u>Ubwoko bw'ihagarikwa</u>: Ihagarikwa ritegetswe na Rwanda FDA

<u>Ikiciro cy'ihagarikwa:</u> Class II

<u>Urwego rw'ihagarikwa</u>: Kugeza ku mavuriro no kubadandaza imiti

Dushingiye ku itegeko **N° 003/2018 ryo kuwa 09/02/2018** rishyiraho ikigo cy'igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) cyane cyane mu ngingo yaryo ya 8, igika cya 2 n'icya 13; no ku mabwiriza No.: CBD/TRG/019 agenga ihagarikwa ry'imiti itujuje ubuziranenge mu gika cyayo cya 6;

Hashingiwe kandi ku itangazo nimero FDISM/PVSM/418/FDA/2023 ryo kuwa 27 Mutarama 2023 ryahagarikaga nimero 2 z'imuti ya Gastro-resistant sodium valproate BP 500mg na Gastro-resistant sodium valproate BP 300 mg y'ibinini ikorwa n'uruganda rwitwa 4 Care Lifescience Pvt Ltd rwo mu Buhinde;

Hashingiwe na none ku busesenguzi bwimbitse bwakozwe n'ikigo cy'igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) n'ibipimo bya laboratwari kuri nimero zitandukanye z'imuti yavuzwe haruguru aho byagaragaje ko iyo miti itujuje ibipimo by'ubuziranenge kandi icyo kibazo kikaba kitari umwihariko kuri nimero runaka;

Kubw'ibyo, Rwanda FDA ihagaritse ikwirakwizwa, ikoreshwa no kwinjiza mu Rwanda nimero zose z'imiti yitwa Gastro-resistant sodium valproate BP 500 mg na Gastro-resistant sodium valproate BP 300 mg tablets ikorwa n'uruganda 4 Care Lifescience Pvt Ltd rwo mu Buhinde:

Izina ry'umuti	**Nimero y'umuti**	**Igihe wakorewe**	**Igihe uzarangirira**	**Uruganda rwawukoze**	**Ikibazo umuti ufite**
Gastro-Resistant sodium valproate tablets BP 300mg	Zose	--	--	4Care Lifescience Pvt ltd/India	Ibinini biravungagurika kandi Bigashonga
Gastro-Resistant sodium valproate tablets BP 500mg	Zose	--	--	4Care Lifescience Pvt Ltd/India	Ibinini biravungagurika kandi Bigashonga

Action to be taken

- Rwanda FDA irasaba abinjiza imiti mu gihugu bose, amashami yose ya RMS Ltd, farumasi ziranguza, izidandaza, amavuriro ya leta n'ayigenga guhagarika gutanga no kugurisha umuti wa Gastro-resistant sodium valproate BP 500mg and 300 mg w'ibinini ukorwa n'uruganda rwa 4Care Lifescience Pvt Ltd rwo mu Buhinde bakawusubiza aho bawuranguriye;

- Abinjije uwo muti mu Rwanda barasabwa guha raporo Rwanda FDA igizwe n'imibare y'ingano y'iyo baranguye, iyo bagurishije, iyagaruwe ndetse n'ingano yose bazaba bafite mu gihe cy'iminsi icumi uhereye ku itariki y'iri hagarikwa.

- Rwanda FDA izamenyesha igihe bizaba byemewe kongera kwinjiza mu gihugu umuti wa Gastro-resistant sodium valproate BP 500mg na 300 mg w'ibinini ukorwa n'uruganda rwa 4Care Lifescience Pvt Ltd rwo mu Buhinde. Bikazaba nyuma y'uko uruganda ruzaba rumaze kugaragaza no gukosora impamvu zatumaga habaho ikibazo cy'ubuziranenge ndetse no kwandikisha umuti mu Rwanda.

Icyitonderwa: Ku bindi bisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa mwahamagara kuri 9707 cyangwa 0789193529; mushobora no kutwoherereza email kuri pv_sm@rwandafda.gov.rw.

Murakoze,

Dr. Emile BIENVENU
Umuyobozi Mukuru

Amafoto y'umuti wahagaritswe.