RWANDA FDA
Rwanda Food and Drugs Authority

Kigali kuwa 27 / 01 / 2023
Ref. N°: FDISM/PVSM/420 /FDA/2023

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

Impamvu: Guhagarika ikwirakwizwa, ikoreshwa no kwinjiza mu gihugu umuti witwa Spamox oral suspension (amoxicillin 125 mg/ 5ml na amoxicillin 250mg/ 5ml) ukorwa n'uruganda rwitwa Sparsh Bio-Tech Pvt Ltd / mu Buhinde.

Dushingiye ku itegeko N° 003/2018 of 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'icya13;

Hashingiwe kandi ku itangazo ryo kuwa 29 Mata 2022 ryahagarikaga nimero 8 z'umuti witwa Spamox oral suspension (amoxicillin 125 mg/ 5ml na amoxicillin 250mg/ 5ml);

Hashingiwe kandi ku busesenguzi bwimbitse bwakozwe n' ikigo cy'Igihugu gishinzwe kugenzura ibiribwa n'imiti (Rwanda FDA) n'ibipimo bya laboratwari kuri numero zitandukanye z'umuti wavuzwe haruguru aho byagaragaye ko iyo miti itujuje ibipimo by'ubuziranenge.

Kubw'ibyo, Rwanda FDA ihagaritse ikwirakwizwa, ikoreshwa no kwinjiza mu Rwanda nimero zose z' umuti witwa Spamox oral suspension (amoxicillin 125 mg/ 5ml na amoxicillin 250mg/ 5ml).

Ibigomba gukorwa

- Rwanda FDA irasaba za farumasi ziranguza, izidandaza, amavuriro ya leta n'ayigenga gusubiza ingano yose y'imiti ya Spamox oral suspension (amoxicillin 125 mg/ 5ml na amoxicillin 250mg/ 5ml) bafite aho bayiranguriye.

- Abinjije iyi miti mu Rwanda barasabwa gutanga raporo kuri Rwanda FDA igizwe n'imibare y'ingano y'iyo baranguye, iyo bagurishije, iyagaruwe ndetse n'ingano yose bazaba bafite mu gihe cy'iminsi cumi n'itanu uhereye ku itariki y'iri hagarikwa.

- Rwanda FDA izamenyesha igihe bizaba byemewe kongera kwinjiza mu gihugu umuti wa Spamox oral suspension (amoxicillin 125 mg/ 5ml na amoxicillin 250mg/ 5ml) ukorwa n'uruganda Sparsh Bio-Tech Pvt Ltd . Bikazaba nyuma y'uko uruganda ruzaba rumaze kugaragaza no gukosora ibibazo byatumaga habaho ikibazo cy'ubuziranenge ndetse no kwandisha umuti mu Rwanda.

Cont

Icyitonderwa: Abashaka gusaba ibisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa bahamagara kuri 0789193529, mushobora no kutwohereza email kuri pv_sm@rwandafda.gov.rw

Murabona amafoto y'ubwoko bw'uwo muti kuri paji ikurikira

Murakoze,

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Photo of recalled SPAMOX (Amoxicillin 125mg/5ml and Amoxicillin 250/5ml)