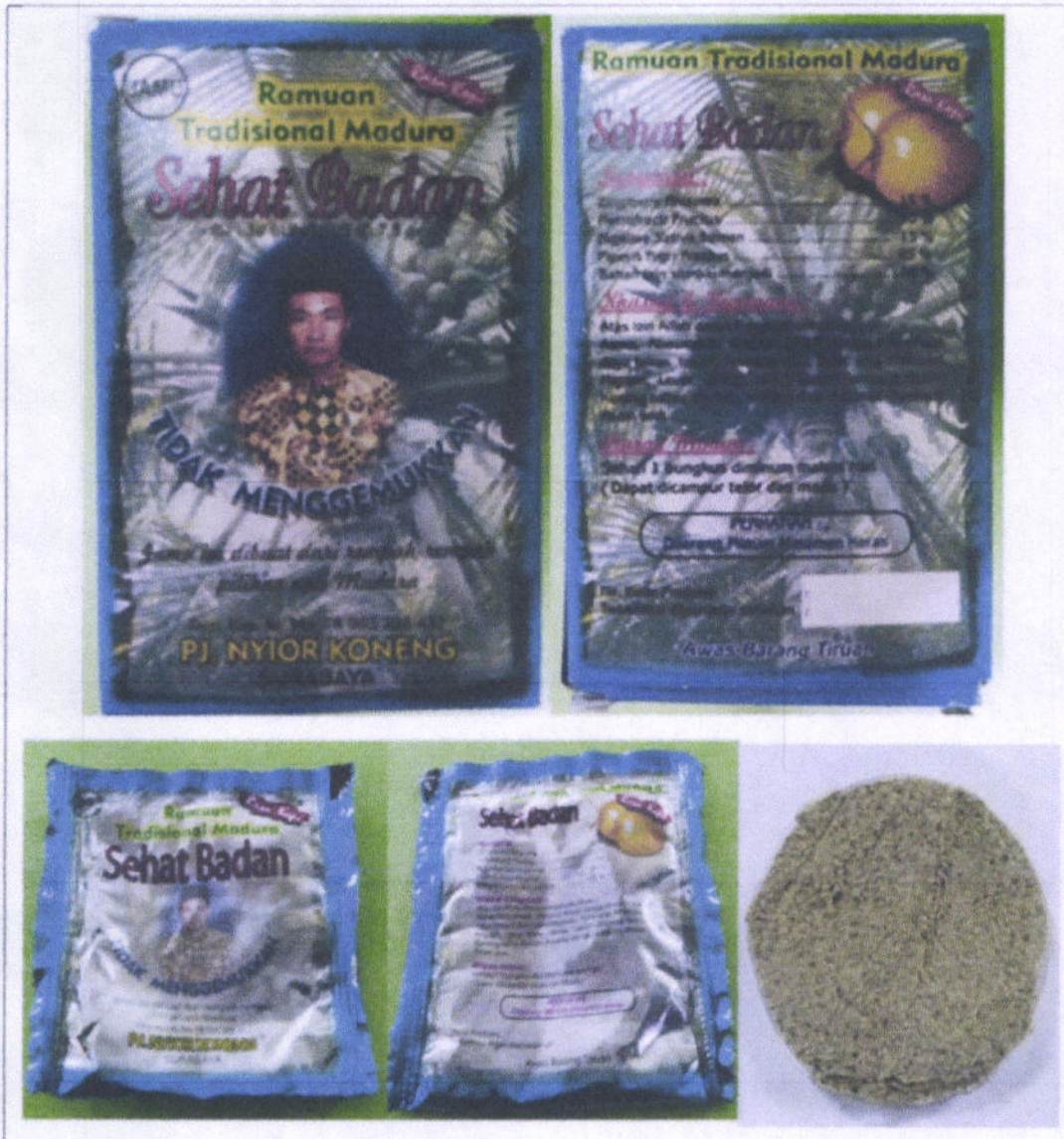
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 OCT 2015

FDA ADVISORY
No. 2015-072

SUBJECT: **Reiteration of Public Health Warning Against the Use of the Unregistered and Adulterated "SEHAT BADAN Powder"**

The Food and Drug Administration advises the public against the use of the following unregistered and adulterated product:



SEHAT BADAN POWDER
Manufactured by PJ. Nyior Koneng – Surabaya Indonesia

Figure 1. Unregistered Product

Unlabeled Repacked SEHAT BADAN POWDER with List of Therapeutic Claims

Figure 2.Unregistered Product

The general public is hereby warned to be vigilant of the abovementioned product. This poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

Recent findings showed the said product is being offered for sale as an unlabeled powder repacked in a small plastic bag with a piece of paper stating the list of therapeutic claims. The illegal marketing of Sehat Badan is still prevalent online and in some areas of the country despite the issuance of FDA Advisory No. 2014-006 and 2014-056 in 2014.

The FDA recent laboratory analysis showed that the product also contains ***Dexamethasone*** in addition to ***Diclofenac sodium***, ***Paracetamol*** and ***Ibuprofen*** that were previously determined.

It must be noted that ***Dexamethasone*** is a steroid, classified as prescription drug while ***Diclofenac sodium***, ***Paracetamol*** and ***Ibuprofen*** are non-steroidal anti-inflammatory drugs (NSAIDs) that are required to be purchased from a licensed drugstore.

The misuse and/or chronic use of steroids like ***Dexamethasone*** may result to serious adverse reactions such as:

- gastrointestinal bleeding and ulcers
- osteoporosis
- muscle weakness
- obesity
- dyslipidemia
- increase risk for infections
- poor wound healing

- if stopped abruptly, could cause withdrawal signs and symptoms such as hypotension, shock and coma.

Moreover, chronic use of NSAIDs like ***Diclofenac sodium***, ***Paracetamol*** and ***Ibuprofen*** could lead to:

- kidney failure
- gastrointestinal ulcers and bleeding
- worsen heart failure
- increase cardiovascular risks
- creates an illusion of getting better while masking the root cause of the illness.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Officers of the Field Regulatory Operations Office (FROO) are hereby ordered to seize the aforementioned unregistered drug product found in the market.

All establishments, outlets and indivduals are hereby warned against selling and/or dispensing the above identified product. Anyone found selling the said product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this product is not sold or offered for sale in their localities or area of jurisdiction.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

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DTN:20150929130131

[1] Pursuant to DPO 2015-1845