

**RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler**

**DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY**

**Rapid Alert Notification of a Medicinal Product Falsification**

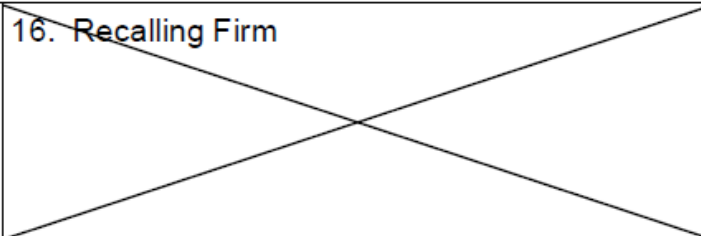
☐ **ASSUMED**

☐ **REASONABLY SUSPECTED**

☒ **VERIFIED**

Regierung von Oberbayern  
Sachgebiet 53.2 – Pharmazie  
Maximilianstraße 39  
80538 München

1. To/Empfänger:		FAX
<input checked="" type="checkbox"/> Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)		0228-207-4636
<input type="checkbox"/> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)		030-18444-30409
<input type="checkbox"/> Paul-Ehrlich-Institut/Bundesamt für Sera und Impfstoffe (PEI)		06103-77-1263
<input type="checkbox"/> Bayerisches Staatsministerium für Gesundheit und Pflege		
2. Classification (not mandatory)	3. Falsification verified	
4. Products: 1. <b>Bitkisel Karışimli Macun Gold Q7</b> 2. <b>Bitkisel Karışimli Macun Epimedyumlu Ginsengli (eniola Özel Üretim)</b> 3. <b>Bitkisel Karışimli Macun Herbal Mixed Paste</b> 4. <b>Jaguar Power Honey</b>	5. Marketing Authorisation Number: * n.a. For use in humans	
6. Brand/Trade Name: same as in point 4. Products	7. INN or Generic Name: The API <b>Sildenafil</b> was detected	
8. Dosage Form: 1. <b>Bitkisel Karışimli Macun Gold Q7: black honey-like mass</b> 2. <b>Bitkisel Karışimli Macun Epimedyumlu Ginsengli (eniola Özel Üretim) chocolate brown inhomogeneous honey-like mass</b> 3. <b>Bitkisel Karışimli Macun Herbal Mixed Paste honey-like inhomogeneous mass</b> 4. <b>Jaguar Power Honey honey</b>	9. Strength: 1. <b>Bitkisel Karışimli Macun Gold Q7 3,9 mg/g (n=3) 1 teaspoon (15g) is equal to 58,5 mg Sildenafil</b> 2. <b>Bitkisel Karışimli Macun Epimedyumlu Ginsengli (eniola Özel Üretim) 4,7 mg/g (n=3)</b> 3. <b>Bitkisel Karışimli Macun Herbal Mixed Paste 5,3 mg/g (n=3)</b> 4. <b>Jaguar Power Honey 5,7 mg/g (n=3) 1 sachet (12,7 g) is equal to 72,4 mg Sildenafil</b>	

10. Batch number (and bulk, if different): 1. n.a. 2. n.a. 3. n.a. 4. Jaguar Power Honey: 190501	11. Expiry Date: 1. 31.08.2025 2. n.a. 3. 18.12.2025 4. 31.01.2026
12. Pack size and Presentation: 1. 1 Package contains 240 g 2. 1 Package contains 240 g 3. 1 Package contains 240 g 4. 1 Carton with 12 sachets of 12,7 g	13. Date Manufactured:* n.a.
14. Marketing Authorisation Holder: n.a.	
15. Manufacturer†: 1. n.a. 2. n.a. 3. n.a. 4. Jaguar Power Honey: <b>Shiny Face Central Trading, Dubai</b>	16. Recalling Firm 
17. Rapid Alert Notification Reference Number: <b>DE_</b>	

#### 18. Details:

On Tuesday, 02.05.2023, and Thursday, 03.05.2023, the Government of Upper Bavaria (Munich) received a request about the above mentioned 4 products by German customs office. It was reported that in the past, Sildenafil has already been found in a product with a comparable name, but different carton. There was also an initial suspicion based on the advertising on the internet. All products were sent from Turkey to Germany; the product Jaguar Power Honey identifies the manufacturer / distributor Shiny Face Central Trading in Dubai.

The products Bitkisel Karışimli Macun Gold Q7, Bitkisel Karışimli Macun Epimedyumlu Ginsengli (eniola Özel Üretim) and Bitkisel Karışimli Macun Herbal Mixed Paste consist of one carton with a glass screw-top jar and a content with ca. 240 g. The products Jaguar Power Honey contains 12 sachets of 12,7 g in a carton. The appearance of the products is shown in the attached pictures.

The products were sent to Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (OMCL) for further analysis in our responsibility. Today, it could be confirmed that all the products contain the API **Sildenafil** with the following concentrations (**analysis report for intra-agency use attached**)

##### Bitkisel Karışimli Macun Gold Q7

**3,9 mg/g (n=3)**

**1 teaspoon (15g) is equal to 58,5 mg Sildenafil**

##### Bitkisel Karışimli Macun Epimedyumlu Ginsengli (eniola Özel Üretim)

**4,7 mg/g (n=3)**

##### Bitkisel Karışimli Macun Herbal Mixed Paste

**5,3 mg/g (n=3)**

##### Jaguar Power Honey

**5,7 mg/g (n=3)**

**1 sachet (12,7 g) is equal to 72,4 mg Sildenafil**

Already with a few grams of the samples, an amount of sildenafil is absorbed that corresponds to the lowest dose of the finished drug product Viagra.

Therefore, all products are classified as a medicinal product. The API Sildenafil is not indicated as an ingredient.

19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):\*  
The products were sent from Turkey.

Sender:

Grandbazaarist  
Yenibosna Merkez MAH  
34197 Bahcelievler

and:

Samet Samet Yilmaz  
Fevzi Cakmak Mahallesi 10553 Sokak  
42060 Konya

Recipients: private

20. Action taken by Issuing Authority: For your information and further action (Turkish and United Arab Emirates competent authorities)

21. Proposed Action: no further delivery to recipients

22. From (Issuing Authority):

23. Contact Person:

24. Signed:

25. Date: 10.05.2023

26. Time: \*

\* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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