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Directorate-General for Trade

Directorate F - WTO, Legal Affairs and Trade in Goods
**Tariff and Non-Tariff Negotiations, Rules of Origin**

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**Trade Policy Committee**

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# NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

***SUBJECT:*** **TTIP Cosmetics** – US Draft Guidance on *"Over-the-Counter Sunscreens: Safety and Effectiveness Data Guidance for Industry*" and *"Nonprescription Sunscreen Drug Products Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act*"

***ORIGIN*:**

Fernando PERREAU-DE PINNINCK
Head of Unit F3, DG TRADE
Tel. +32 229 61932
E-mail: Fernando.PERREAU-DE PINNINCK@ec.europa.eu@ec.europa.eu

Ivone KAIZELER
Unit F3, DG TRADE
Tel. +32 2 296 20 49
E-mail: Ivone. Kaizeler@ec.europa.eu

***OBJECTIVE: For information/For comments***

***REMARKS:***

The US Food and Drug Administration (FDA) published by the end of November 2015 in the US Federal Register two important draft guidance documents: *"Over-the-Counter Sunscreens: Safety and Effectiveness Data Guidance for Industry*" and *"Nonprescription Sunscreen Drug Products Content and Format of Data Submissions To Support a GRASE Determination Under the Sunscreen Innovation Act*". Deadline for stakeholder's comments in the US Federal Register is 22nd January 2016.

These draft guidance documents determine which data needs to be submitted for FDA to determine the safety and effectiveness of a sunscreen ingredient. As several EU cosmetic products contain sunscreens/UV filters, these guidance documents will have implications for the exports of EU cosmetic products to the US.

The full text of the proposed draft guidance is available at:

- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM473464.pdf

- http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM473772.pdf

The European Commission would welcome comments from Member States on these two draft guidance documents the latest by **20 January 2016**. Comments should be forwarded to DG GROW (GROW-COSMETICS-AND-MEDICAL-DEVICES@ec.europa.eu) and to DG TRADE (TRADE-F3-SECRETARIAT@ec.europa.eu).