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May 11, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane / Room 1061
Rockville, MD 20852

RE: Comments – Docket No. 2002N-0278

To Whom It May Concern:

On December 12, 2003, the new section 301(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)) was implemented to support section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Since that time, Sigma-Aldrich Corporation has experienced numerous delays in clearing our inbound freight through the port of Huntsville, Alabama. Despite our lengthy attempts to resolve these issues, our sales to U.S. customers for these imported products have suffered and we feel our relationships with both U.S. Customs and our customers have been negatively impacted.

On April 14, 2004, the comment period was re-opened for the prior notice interim final rule (IFR) that was originally published in the Federal Register on October 10, 2003. In response, we would like to submit a comment pertaining to the FDA's current procedure for flagging imported materials that may require prior notice submissions, codes FD3 & FD4.

Our freight forwarder in Huntsville uses the Automated Broker Interface (ABI) of the Automated Commercial System (ACS) to clear our inbound freight shipments. Our forwarder has confirmed that the ABI system automatically requires them to enter the prior notice information for any materials that contain a Harmonized Tariff Schedule number (HTS) that is flagged as FD3 or FD4. Thus, they have asked us to submit prior notice for all of these materials.

Sigma-Aldrich is a leading Life Science and High Technology company. Its biochemical and organic chemical products and kits are used worldwide in scientific and genomic research, biotechnology, pharmaceutical development, the diagnosis of disease and chemical manufacturing. Our customers are life science companies, universities, government institutions, hospitals and in industry. Over one million scientists and technologists use our products.

Upon reviewing the definitions of 'food' and 'food products' in the FD&C Act, we have determined that only a small number of Sigma-Aldrich products meet this definition and therefore would require a prior notice submission under the Bioterrorism Act. The majority of our products do not meet this definition and would not require a prior notice submission. However, several of these non-regulated products are coded with an HTS number that is flagged FD3 or FD4 and there is no exception process available for us to utilize. For example, we import pre-labeled 1 g vials of Vitamin D in powder form for use in the

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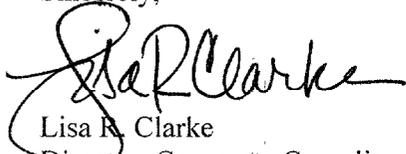
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scientific research community. This product does not meet the definitions for 'food' or 'food product' in the FD&C Act, yet we are being required to submit prior notice entries before we can import this into the U.S.

On or around May 12, 2004, the FDA changed the codes on several Harmonized Tariff Schedule numbers (HTS) from FD4 to FD3. These HTS numbers are now listed on the FDA's website, under the section titled 'Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators' (<http://www.cfsan.fda.gov/%7Epn/pnoview.html>), marked with an asterisk. We have reviewed our list of non-regulated products that contain an HTS that is flagged FD4 and would like to ask FDA to change the codes on an additional 49 HTS numbers, from FD4 to FD3, so that we may import these materials without prior notice submissions. We have attached the list of these HTS numbers to this letter, indicating the number of Sigma-Aldrich products that are currently classified in each HTS.

We appreciate your consideration in this matter and look forward to your response. Please do not hesitate to contact me at the below numbers if you have any questions about this request or if you need additional information.

Sincerely,



Lisa R. Clarke
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Sigma-Aldrich Corporation

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Request to FDA - Change FDA Flags from FD4 to FD3
Sigma-Aldrich Corporation

FDA Flag	HTS Desc	HTS Code	# of SIAL mats
FD4	OTHER ALBUMINS INCLUDING CONCENTRATES OF WHEY ETC.	3502.90.0000	884
FD4	VITAMIN C (ASCORBIC ACID) AND ITS DERIVATIVES	2936.27.0000	143
FD4	VITMN B6(PYRIDOXINE/RELATD COMPDS W/VITMN B6 ACTVTY)..DERIVS	2936.25.0000	78
FD4	VITAMIN E(TOCOPHEROLS & RELATD COMPNDNS W/VIT E) & ITS DERIVS	2936.28.0000	67
FD4	VITAMIN B 2 (RIBOFLAVIN) AND ITS DERIVATIVES	2936.23.0000	66
FD4	D- OR DL-PANTOTHENIC ACID (VITAMINS B 3 OR B 5) & ITS DERIVS	2936.24.0000	60
FD4	VITAMIN B 1 (THIAMINE) AND ITS DERIVATIVES	2936.22.0000	58
FD4	FOLIC ACID	2936.29.1000	58
FD4	VIT B12(CYANOCOBALAMIN/RELATD COMPNDNS W/VIT B12 ACT)..DERIVS	2936.26.0000	53
FD4	GUAIACOL AND ITS DERIVATIVES	2909.50.2000	48
FD4	EGG ALBUMIN, DRIED	3502.11.0000	41
FD4	CASEIN, CASEINATES AND OTHER CASEIN DERIVATIVE, OTHER	3501.10.5000	25
FD4	FLOURS, MEALS OF OIL SEEDS OR OLEAGINOUS FRUITS OF SOYBEANS	1208.10.0000	24
FD4	PROVITAMINS, UNMIXED	2936.10.0000	24
FD4	BIOTIN	2936.29.5030	24
FD4	SUGARS, INCLUDING INVERT SUGAR, OTHER	1702.90.9000	23
FD4	SUGAR, CANE, RAW, HUMAN CONSUMPTION, OR FOR EXPORT	1701.11.2000	22
FD4	VITAMINS D AND THEIR DERIVATIVES	2936.29.5020	21
FD4	CASTOR OIL AND ITS FRACTIONS-CRUDE OIL	1515.30.0000	19
FD4	OTHER STARCHES, OTHER	1108.19.0090	17
FD4	CEREAL FLOUR OTHER THAN WHEAT: CORN (MAIZE) FLOUR	1102.20.0000	14
FD4	NIACINAMIDE	2936.29.1530	14
FD4	VITAMINS AND THEIR DERIVATIVES, UNMIXED; OTHER	2936.29.5050	14
FD4	EXTRACTS AND JUICES OF MEAT	1603.00.9010	13
FD4	MILK ALBUMIN, INCLUDING CONCENTRATES OF >=2 WHEY PROTEINS	3502.20.0000	12
FD4	COTTONSEED OIL OTHER, (FULLY REFINED, WASHED, BLEACHED OR DEOD.	1512.29.0040	9
FD4	GERM OF CEREALS, WHOLE, ROLLED, FLAKED OR GROUND	1104.30.0000	8
FD4	COCONUT (COPRA) OIL AND ITS FRACTIONS, OTHER THAN CRUDE OIL	1513.19.0000	7
FD4	SESAME OIL AND ITS FRACTIONS, NOT CHEMICALLY MODIFIED	1515.50.0000	7
FD4	VITAMINS & THR DERIVS, UNMIXED:OTH, NSPF; AROMATIC/MODIFD ARO	2936.29.2000	7
FD4	OLIVE OIL & ITS FRACTIONS, NOT VIRGIN, OTHER, NT CHEM. MODIFIED	1509.90.4000	6
FD4	OILS FRM.OLIVES & BLENDS, OTHER, WEIGN.WT.; CONT. >= 18 KG.	1510.00.6000	5
FD4	CULTIVATED GINSENG ROOTS, FRESH/DRIED	1211.20.0020	4
FD4	SUNFLOWER-SEED OIL, OTHER, NOT CHEMICALLY MODIFIED	1512.19.0020	4
FD4	SAFFLOWER OIL, OTHER, NOT CHEMICALLY MODIFIED	1512.19.0040	4
FD4	PROVITAMINS & VITAMINS, NATRL/REPR., OTH, INCL NATRL CONCNTRTS	2936.90.0000	4
FD4	MALT, NOT ROASTED	1107.10.0000	3
FD4	PEANUT (GRD-NUT)OIL REFINED OR NOT, BUT NOT CHEM.MODIF;OTHER	1508.90.0000	3
FD4	OTHER BARLEY - OTHER	1003.00.4090	2
FD4	FLOURS& MEALS OF OIL SEEDS OR OLEAGINOUS FRUITS, (NO MUSTARD)	1208.90.0000	2
FD4	SEAWEEDS AND OTHER ALGAE, NSPF	1212.20.0000	2
FD4	COD FISH-LIVER OILS AND THEIR FRACTIONS, NT CHEMICAL MODIFIED	1504.10.2000	2
FD4	CORN OIL, OTHER, FULLY REFINED, WASHED, BLEACHED OR DEODOR	1515.29.0040	2
FD4	FRUCTOSE, DRY STATE MOR THN 50% BY WT FRUCTOSE, OTHER	1702.60.4090	2
FD4	ALMONDS OTHERWISE PREP/PRES WHETHER OR NOT CONT ADDED SUGAR	2008.19.4000	2
FD4	BAGASSE AND OTHER WASTE OF SUGAR MANUFACTURE	2303.20.0040	2
FD4	ANIMAL FAT/OILS, AND THEIR FRACTIONS CHEMICALLY MODIFIED	1516.10.0000	1
FD4	SUGR, CN/BT, RAW, NO COLOR, NO ADD FLVR, OTHER	1701.11.5000	1
FD4	GLUCOSE & SYRUP W/<20% DRY WT OF FRUC, NOTE 9, OTHER	1702.30.2800	1