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Additional Information to Prior Announcement

ASX Announcement

26 May 2021

Holista Colltech Limited (ASX: HCT, "Holista" or "the Company") wishes to provide the following additional information at the request of the ASX to the announcement released on 13 May 2021 entitled "Collagen Market Update".

1. The cosmetic manufacturer testing Holista's collagen product is Guangzhou Sinbio Cosmetic Co Ltd, which is a Chinese State-Owned Enterprise (SOE) and is an existing customer of Mutiara.

2. The countries / jurisdictions in which Holista's collagen is currently listed or authorised as 'cosmetic grade' are Australia, New Zealand, Thailand, Malaysia, Singapore, Philippines, Vietnam, Taiwan and the United States.

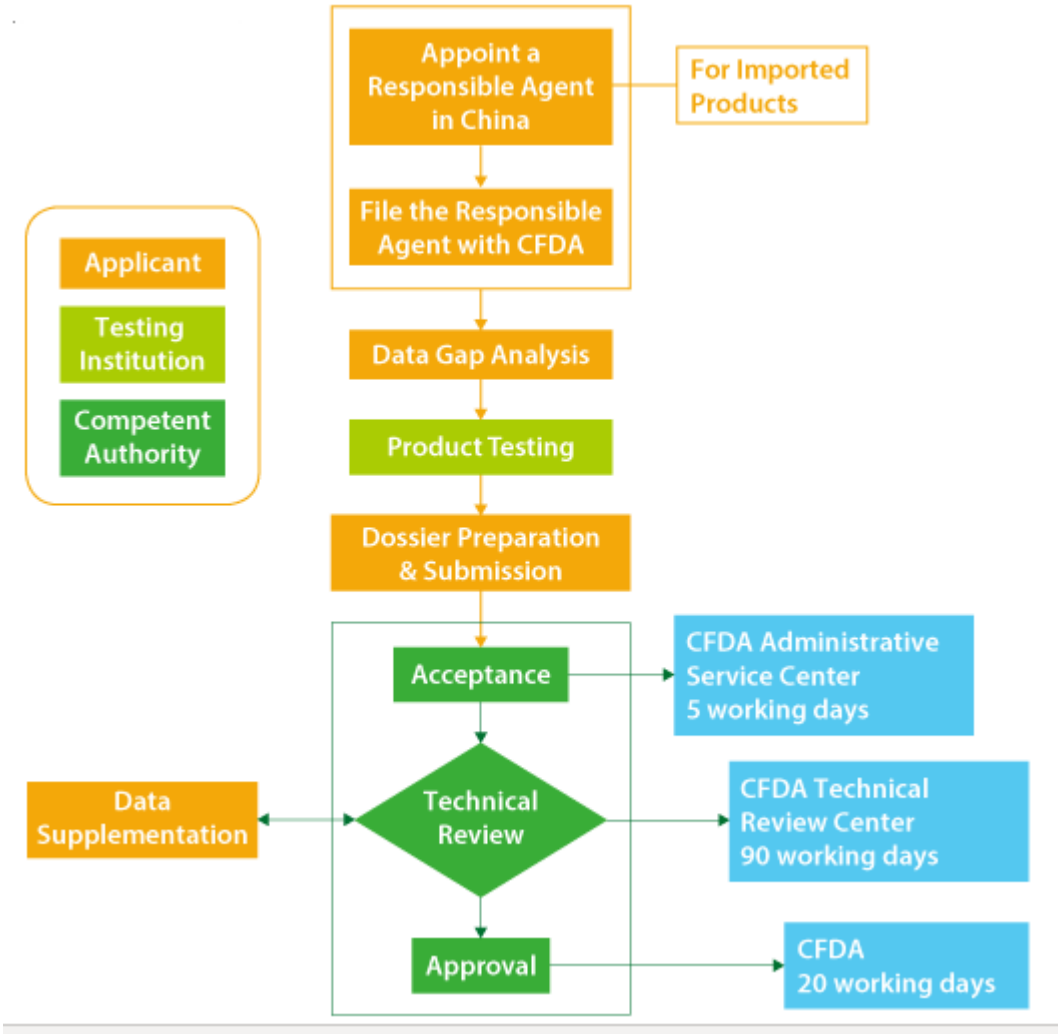
3. The trials are to ensure that Holista's product conforms with all the regulatory requirements of cosmetic usage in China in terms of safety and efficacy. The regulatory hurdles are lower than for medical-grade products, and importantly, Holista's collagen is derived from sheep and lamb which have long been exported to China without issues or restrictions. The Distribution Agreement begins after all the approvals in China have been obtained.

   As stated in the original announcement, Holista is not involved in the Chinese regulatory approvals process as that is the sole responsibility of Mutiara's Chinese customer. Mutiara has informed Holista that cosmetics and cosmetic ingredients are regulated by the laws in China that are listed below. It typically takes 3 to 6 months to obtain all regulatory certificates for ordinary cosmetics.

   The following are the specific approvals that Mutiara must obtain in order for the collagen to be sold in China:

   I. Safety and Technical Standards for Cosmetics 2015 (STSC 2015)
   II. INCI Chinese Version 2010 Catalogue of Standard Chinese Name of International Cosmetic Ingredients
   III. Provisions for Management of Cosmetic Registration and Notification Dossiers
   IV. Standards for Cosmetic Efficacy Claim Evaluation

The application process is as follows



There are three authorities for the cosmetic sector and these are detailed below:

a. **State Administration for Market Regulation (SAMR)**
Formerly known as the Chinese Food and Drug Administration ("CFDA"), SAMR takes overall charge of market supervision of food, cosmetics, pharmaceuticals, and medical devices.

b. **National Medical Products Administration (NMPA)**
NMPA is established under the governance of SAMR and is responsible for the registration of imported/domestic special cosmetics, the notification of imported general cosmetics, and the registration and notification of new cosmetic ingredients.

c. **General Administration of Customs (GAC)**
GAC is responsible for the customs import and export inspection and quarantine of cosmetics.

The following are specific approvals needed and estimated timeline :

	Regulation	Estimated duration (months)	Authority	Started? Yes / No	Status	Minimum Requirements
1	Safety and Technical Standards for Cosmetics 2015 (STSC 2015)	4 months	NMPA	Yes	Sample evaluation	China Cosmetic Safety Technical requirements: - 1. The limit of heavy metal lead is 10mg/kg. 2. The limit of heavy metal arsenic is 2mg/kg. 3. The limit of heavy metal cadmium is newly set as 5mg/kg. 4. The limit of toxin dioxane is 30mg/kg. 5. Absence of asbestos 6. Skin safety testing (direct application of the Collagen and in formulation) 7. Skin Sensitivity testing (non-irritation after 1 min / 60 mins / 24 hours) 8. Non irritation of mucous membranes testing 9. Corneometry based hydration determination (% versus placebo)
2	INCI Chinese Version 2010 Catalogue of Standard Chinese Name of International Cosmetic Ingredients	3 to 6 months	NMPA / SAMR	Yes	Dossier preparation	1. Creation of Data for Inclusion in the Catalogue of Cosmetic Ingredients (INCI). 2. Comparison versus standards cosmetic ingredients 3. Providing supporting data on skin moisturising and skin enhancing claims (data already available but Chinese authorities may insist on local Chinese trials) 4. All data available on file for test done in country of origin (Australia)
3	Provisions for Management of Cosmetic Registration and Notification Dossiers	3 months	SAMR / GAC	No	Not initiated	1. Adopting comparative data in the Chinese Registry with other collagen already registered in China 2. Collection of similar cosmetic collagen data available in important reference countries – United States, Canada, Japan, United Kingdom, Germany, Switzerland, Australia and France
4	Standards for Cosmetic Efficacy Claim Evaluation	4 months	NMPA	No	Finished products send for evaluation	Safety Assessment on product formulation:- A. Hazard Assessment (1)Acute toxicity (2) Irritating/corrosive (3) Allergenicity (4) Phototoxicity (5) Light pervert reaction (6) Genetic toxicity (7) Repeated dose toxicity (8) Reproductive development toxicity (9) Chronic toxicity /carcinogenicity (10) Toxic generation dynamics (11) Crowd safety information B. Dose Reaction Assessment C. Exposure Requirements D. Risk Characteristic E. Risk Control Measures

4. The positive outcome from the trials refers to Holista's collagen receiving all such approvals from Chinese regulators and being granted an export permit from the GAC. These approvals are to be obtained from the NMPA under China's Cosmetic Supervision and Administration Regulations.

5. This positive outcome is the only condition for Mutiara committing to purchase the annual production quantities previously advised.

   Export permits are required as part of “all necessary approvals” and Mutiara and its customers will be responsible for obtaining all export permits. The shipment frequency and order size will depend on the purchase orders (POs) placed by Mutiara and Holista’s production capacity to fulfill the PO. Mutiara will place the first batch of POs when Chinese regulatory approvals are obtained.

6. The Distribution Agreement includes the following terms:
   ‘Minimum Order Quantity’ is defined as ‘the smallest size of a shipment”. This is set at 1 tonne (1000kg)’. ‘Payment Terms’ is defined as per Schedule 1 of the Agreement being 50% deposit upon order and 50% before delivery. ‘Minimum Annual Performance Requirements’ are defined in Schedule 3 of the Agreement.

   Mutiara is to pay a 50% deposit of $1.8 million to Holista within 14 days of obtaining Chinese regulatory approvals. This deposit is non-refundable should Mutiara fails to place orders for the full amount of 48 tonnes during the first year. The balance 50% for the first year of 48 tonnes shall be paid as per individual orders placed by Mutiara before Holista releases the Product for shipment.

   The payment structure that applies to the individual PO over the subsequent years of the agreement will be 50% down payment accompanying each PO and the remaining 50% before Holista releases the products.

   If at any time over the contract duration Mutiara fails to purchase the agreed minimum quantity as per the Distribution Agreement, the agreement shall be terminated and Mutiara will lose the exclusivity of distributing Holista’s collagen in China.

7. Holista will refurbish the existing plant to ensure it can meet the production requirement of 48 tonnes in the first year. The refurbishment entails replacing or upgrading ageing equipment and installing additional storage tanks and expanding the effluent plant. The plant will have to be completely shut for up to four months and the refurbishment will cost approximately $1.5 million. This will be funded through a mixture of 50% deposit from Mutiara for the first-year orders and cash flow from Holista’s operations. As at 31 March 2021, Holista has $1.8m cash deposits.

   Depending on when Mutiara obtains all the Chinese government approvals and depositing the 50% of first year orders to HCT, the refurbishment plan could begin sometime between September to November 2021. The plant would likely to resume operations between December 2021 and January 2022. Prior to the shutdown, Holista will make buffer stocks of finished product for shipment to existing customers and for the initial POs from Mutiara.

   The expansion of the plant to scale up production from Year 2 onwards will be progressively funded from cash received through the POs from Mutiara and Holista’s internal resources.

The following is the proposed scale up plant capacity by year :

Year	Investment Required in Plant (estimated ($'million)	Plant Capacity (in Tonnes)	Sales Quarter 1 to Mutiara (in Tonnes)	Sales Quarter 2 to Mutiara (in Tonnes)	Sales Quarter 3 to Mutiara (in Tonnes)	Sales Quarter 4 to Mutiara (in Tonnes)
1	1.5	48 Note 1	6 Note 2	14	14	14
2	1.7	144 Note 3	36	36	36	36
3	2.6	288 Note 4	72	72	72	72
4	1.2	576 Note 5	144	144	144	144
5	0.5	576 Note 5	144	144	144	144

Note 1 : After refurbishment
Note 2 : From the buffer stocks built up between May 2021 and the shutdown
Note 3 : After progressive expansion from cashflows received during year 1
Note 4 : After progressive expansion from cashflows received during year 2
Note 5 : After progressive expansion from cashflows received during year 3

The subsequent expansion will consist mainly of adding duplicate production lines in line with the capacity of existing tanks, moving to 3 shifts per day, upgrading pumping and filtration equipment to improve the throughputs and expanding the building workspace, clearing all the food grade equipment space and maximise cosmetic production capacity, creating additional lines and building an extension to the plant.

As part of the plant expansion, the Company will appoint external consultants to advice and administer all the relevant building, machinery and regulatory requirements needed.

Holista is confident all the plant expansion funding will be sourced from the cashflows generated under this contract.

8. Epidermal Growth Factor (EGF) is increasingly scrutinised by regulators worldwide. See Note 1, by way of example South Korea. Collagen is a powerful moisturising agent when applied to skin and increases the skin's suppleness and tone as shown by numerous studies conducted by third parties in Germany and the US (Note 2). This is why the global collagen market continues to grow despite the introduction of newer alternative ingredients (Note 3).

9. Holista's patent expires in 2023 and the Company is in the process of extending and strengthening the patent with a view to filing additional patents around the original patent.

10. The Distribution Agreement can be terminated in circumstances when the minimum annual order requirement is not met, where either party commits a material breach of contract, becomes insolvent or put under administration from actions brought on by either creditors or the courts or Mutiara fails to provide the 50% down payment for the first year's 48 tonnes within 14 days of the approvals being received.

This announcement has been approved by the Board of Directors.

-Ends-

Note 1: https://www.cosmeticsdesign-asia.com/Article/2020/07/07/South-Korea-tightens-down-on-EGF-cosmetic-products-with-inappropriate-claims
Note 2: Report by Dermatest GmbH 19 April 2007 p23
Report by Cantor Research Laboratories Inc 9 February 2007 p5
Report by Ovine Collagen As An Alternative to Bovine Collagen - Akron General Medical Center p9
Note 3: https://www.databridgemarketresearch.com/reports/asia-pacific-collagen-market

About Holista Colltech Limited

Holista Colltech Ltd ("Holista") is a natural wellness company with the following divisions:

- Dietary Supplements
- Healthy Food Ingredients
- Ovine Collagen
- Infection Control Solutions

Holista has a global collaboration with Global Infection Control Consultants LLC to use Path-Away®, a plant-based solution that is proven to kill a broad spectrum of microbes. The all-natural alcohol-free active ingredient is used in Holista's range of disinfectant products under the NatShield™ brand.

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